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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

H.R. 5233

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1987, AND FOR OTHER PURPOSES

PART 4—(Pages 1-960)

Nondepartmental witnesses

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

THURSDAY, APRIL 24, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:03 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Specter, and Proxmire.

NONDEPARTMENTAL WITNESSES

Senator WEICKER. The subcommittee will come to order.

This morning is our first of 7 days of public witness hearings. We will be hearing first from public witnesses from the Department of Labor followed by public witnesses from the Centers for Disease Control [CDC] and the National Cancer Institute.

To my right, you will see two lights. You will be starting when you see the green light. You will have 4 minutes to summarize your statements. I would appreciate it if your statement would be finished when you see the red light. I really don't like to use this system but we, even now, have had to limit those that the committee can hear. I think it is probably the only committee in the Congress that has 7 days of public hearings.

So we are trying to get as much input as possible. It is really not so much a matter of courtesy to the Chair as it is a matter of courtesy to the other witnesses that those that are testifying will restrict themselves to the 4 minutes allotted.

If you want to talk more than 4 minutes, then I suggest you run for office and become a U.S. Senator. [Laughter.]

STATEMENT OF MARY JANE MEEHAN, DIRECTOR, DIVISION OF EMPLOYMENT AND TRAINING, STATE OF NEW JERSEY

Senator WEICKER. Our first witness is Mary Jane Meehan, director of employment and training from the State of New Jersey.

Ms. MEEHAN. Good morning.

I am director of the New Jersey Division of Employment and Training, and I am here on behalf of the National Governors Association to emphasize the need for continued financial support for investment programs in employment and training, specifically, the Job Training Partnership Act [JTPA].

I would first like to say that the Governors have supported measures to attack this critical problem of the Federal deficit and are doing their best to handle the situation but feel strongly that major shifts of responsibility of the Federal Government to the States, based on the assumption that there are State surpluses, is just not accurate and is a misconception.

There are at least 17 States that had to already cut their budgets to prevent State deficits. In terms of the Job Training Partnership Act specifically, the NGA policy is to freeze the 1987 appropriation at the 1986 level and to try and keep investment programs like this still supported and enhance the productivity of the country.

There are a couple of issues on JTPA that I would just like to speak about very briefly. You have my printed testimony.

This partnership, I feel, from a State director's point of view, has been extremely successful. I have seen the effects of it first hand, and what worries me the most is that what I think is the essence to its success, the input from the private sector, and their commitment to it will be eroded as the budget cuts are continually impacting on this program. That concerns me the most.

I think it is important to recognize that out of the title II–A budget, only 3 to 4 percent of the eligible population is being served, and if cuts go through for programs like WIN, the Job Corps, and the Summer Youth Employment Program, it is impossible and unrealistic to think that this program can pick up the slack of those and not affect the service level to those groups and to the eligible population that it is already serving.

I have some additional points, too, that I would like to make on the title III program, the Dislocated Worker Program and on the Summer Youth Program. There is a proposal now by the Department of Labor that calls for discretionary spending of the title III dollars to be held by the Secretary and put out to States as needed. From someone who has had a lot of experience, unfortunately, with this dislocated program in New Jersey, we have had over 200 plants close in the last 1½ years and over 10,000 individuals affected by those closings.

It is impossible to think you can address worker adjustment strategies without having a system in place, without early intervention, and without even thinking of prelayoffs. So to think that targeting dollars when the need arises and going through the system of the Federal Government, I think, is going to be impossible to deal with the program and make it more and more difficult.

On the Summer Youth Program, there is also a proposal to target to the larger cities where the problem seems to be the greatest. It is hard to argue the logic of that. It makes allot of sense, except that what it does is ignore the fact that the problem is very severe in the rest of the country, not just in the larger cities, especially when summer growth dollars are being used to prevent dropouts and improve literacy.

The way we are doing it in New Jersey is, we have 15 of 19 service delivery areas using the Summer Youth Program money for classroom needs of training and addressing the dropout situation.

So to think that we can target the money to these areas and ignore the rest of the country is really disturbing to me.

In conclusion, I would just like to say that this investment program is extremely important. Every time we cut dollars, we are going to cut the service to individuals. Fewer will be served. Fewer handicapped people will able to be competitive. Fewer dislocated workers will be able to address adjustment problems. It is not going to be a saving in the end. We are going to increase dependency on the Government if we cut these programs.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. I appreciate your testimony. Your testimony in its entirety will be included in the record.

Ms. MEEHAN. OK.

[The statement follows:]

STATEMENT OF MARY JANE MEEHAN

INTRODUCTION

Good morning. My name is Mary Jane Meehan. I am Director of the New Jersey Division of Employment and Training. This morning I am pleased to testify on behalf of the National Governors' Association on the Labor, Health and Human Services, and Education appropriation for Fiscal Year 1987. Specifically my testimony will provide the states' perspective on why sustained federal financial support for employment and training programs -- in this case, the Job Training Partnership Act -- is important for the continued evolvement of a strong public/private partnership to strengthen our nation's economy.

GOVERNORS' POSITION ON THE BUDGET

Let me begin by saying that the Governors recognize the critical importance of reducing the federal deficit and they have publicly supported a variety of proposals to assure a balanced package of spending and revenue changes. They agree that federal aid to state and local government cannot be exempt from consideration. However, they are opposed to large shifts in current federal responsibilities to state government based on the misconception that states have fiscal surpluses. Clearly, the current fiscal condition of the states does not provide a bright picture. Already, at least 17 states have been forced to cut their current year's budget to avert impending deficits.

The NGA policy position on the budget calls for freezing 1987 appropriations at the 1986 level for non-defense discretionary spending. The Governors feel strongly that the burden of budget cuts not fall on already hard pressed lower income Americans and that special consideration be given to "investment" programs such as job training and education which enhance the productivity of this country.

THE JOB TRAINING PARTNERSHIP ACT

The Job Training Partnership Act (JTPA) is unique among federal legislation in that it has created a viable, and potentially very significant three-way partnership between the federal government, the states and the private sector for the design, delivery and management of training, employment and related educational services in the country. Consistent with the principles of federalism, JTPA has assigned shared responsibilities for carrying out the intent of the Act to the federal government and the states.

The Act has provided states with welcome policy latitude to mesh JTPA goals with state priorities related to economic development, educational and welfare reform. Some 15 states now have state appropriated programs dealing with various aspects of worker adjustment that are being effectively coordinated with JTPA Title III activities.

For example, recognizing that the employment and training needs of New Jersey residents could not be fully met through existing JTPA and other programs, the New Jersey legislature approved a bill in September, 1983 which supplements JTPA in a variety of ways. It identifies target groups not in JTPA and it permits the use of these funds to help meet the JTPA Title III match requirements. The bill became known as the New Jersey Job Training Program. Since JTPA and NJJTP were both scheduled for implementation at the same time, it was decided that funds for Title III and the $4 million appropriated for NJJTP would both be given to the Service Delivery Areas (SDAs) by formula with 75% going to the SDAs and 25% held at the State level.

Other states are combining JTPA and other resources to address youth unemployment and other critical state and local concerns. JTPA has also provided states with useful management tools in the form of the performance standards system and state planning, technical assistance and oversight functions to promote both the efficiency and effectiveness of the services provided.

At the local level, JTPA has created a hospitable environment for private sector involvement in the policy making process. Throughout the country, private sector volunteers have responded to this real invitation with a sustained and high level commitment of time and effort. The Private Industry Councils (PICS) created through the Act have shown the potential of becoming the much needed convening body to effect desired coordination within JTPA and between JTPA and related systems. I believe it is fair to say that the Act has successfully achieved a good balance between emphasis on fiscal and programmatic accountability, the principles of partnership, and the need for local diversity through decentralized decision-making.

These important structural developments within the states facilitated to a significant extent by JTPA, make JTPA more important within the federal intergovernmental system than its past or current funding level would suggest. States and localities have used available JTPA resources to leverage state and local resources and make mainstream education and other delivery systems more responsive to the needs of at-risk individuals such as those eligible for participation in JTPA. Strategic use of limited resources to accomplish these broader institutional change goals, while at the same time serving the immediate needs of clients, is not easy. It requires careful planning and patience.

A unique initiative undertaken between the New Jersey Department of Labor and the New Jersey Department of Education is designed to foster a linkage between the SDAs and Local Education Agencies (LEAs) using the cooperative education program. The linkage of JTPA exemplary youth programs with cooperative education programs operated by Local Education Agencies provides a means for delivering a unified and coordinated employment training program for JTPA eligible in-school youth. The linkage enables the SDA to broaden the kinds of services it can deliver to disadvantaged youth. The LEA can expand its cooperative education programs by utilizing resources from the SDAs. The cooperative education approach to providing vocational training combines wages from a job, academic and vocational training, and a high school diploma and each provider will pay for a portion of these services.

Nearly 8% of the New Jersey JTPA caseload is composed of handicapped persons. A joint venture of the New Jersey Commission for the Blind and Visually Impaired, the Private Industry Councils of Bergen and Passaic counties and Bergen Community College, funds jobs for the blind and visually impaired and provides training, including job seeking skills, in the computer and word processing fields.

We believe our state and local initiatives to use JTPA as a focal point for change will be enhanced by our federal partner's policy and other support for such activities.

As the "managing partners" in the JTPA system, we feel that we need to raise several funding-related concerns with the Subcommittee.

OVERALL JTPA FUNDING LEVEL

Even without the President's proposed budget cuts and the budget reductions resulting from Gramm-Rudman-Hollings, the real value of the federal investment in employment and training is being eroded by inflation. The JTPA system, which by all accounts is successfully working in communities throughout the country, could not be sustained with its present delivery system of approximately 600 Service Delivery Areas and Private Industry Councils if any additional reductions were to be made.

Furthermore, despite the potential of JTPA as an organizing force within states, it is important to recognize that even at PY 1985 funding levels, there were only sufficient resources in Title II-A, for instance, to serve between three and four percent of the eligible population. This means that it is unreasonable to expect JTPA Title II-A to absorb proposed cuts in such programs as Job Corps, WIN and the Summer Youth Employment Program (SYEP) authorized under Title II-B without causing a reduction in service to other groups now being served.

TITLE III

The Title III Dislocated Worker program has become an integral part of every state's strategy for addressing worker dislocations which continue to occur throughout the country in large urban areas, on farms, and in many different kinds of communities in between. Substantial funding cuts imposed on the program last year will absorb funds unexpended as a result of slow initial program start-up and in those states that have expended high proportions of their allocations, will result in sharp decreases in the level of services provided. For the most part, states are not in a position to absorb these cuts with increased state funding.

We are concerned that the Department of Labor's proposal to allocate all Title III resources available in PY 1987 on a discretionary basis from the national level will seriously undermine the states' ability to plan for and institutionalize worker adjustment strategies. It is difficult to argue with the stated objective of targeting limited resources on those areas and industries in particular need, but there is little or no evidence that a federal system could or would target resources more efficiently especially without a federal plant closing notification system. Should resources be distributed as proposed, inequities no doubt would occur exacerbating existing problems. We believe that the needs of our nation's dislocated workers can be better served by maintaining the authorizing committees' legislated 75%-25% split between resources allocated to states by formula and discretionary resources retained at the federal level. The absence of a formula allocation would prevent states from moving ahead with further development of early warning systems and institutionalization of flexible and timely response mechanisms. In addition, the shift to discretionary funding only would slow the response time of states during the critical early weeks of a layoff situation and therefore reduce the effectiveness of the program.

SUMMER YOUTH EMPLOYMENT PROGRAM

We are distressed at the substantial cuts proposed in the Summer Youth Employment Program (SYEP) especially in light of the continuing alarming statistics on youth nemployment and educational deficiencies. The recommendation for reduced SYEP funding seems glaringly inconsistent with the Administration's new emphasis on addressing illiteracy. We are concerned, too, with the Department of Labor's proposal to target all Calendar 1988 Summer Youth Employment Program funds to the largest cities with the highest concentration of unemployed youth. Although we recognize the need to find better ways of addressing the youth employment problem in areas with high concentration of need, we do not believe that vast areas of the country with substantial needs of their own should be left without SYEP resources. This program is an important community resource for combatting priority literacy and dropout problems and therefore needs to be made available throughout the nation.

New Jersey has sought to upgrade the type of training provided by the Title IIB summer program. We have encouraged the achievement of youth employment competencies as performance indicators and for Calendar 1986 have implemented a policy requiring that he SDAs expend a minimum of 20 percent of their Title IIB allocation on classroom training which is curriculum based. This will, in our opinion, accelerate a trend which already exists. In last year's summer program there was a 63 percent increase in the number of classroom training and vocational exploration slots available for summer youth program participants over the previous year. Six SDAs provided literacy/remedial education components. A recent survey indicated that 15 of the 19 SDAs in New Jersey will be providing a literacy/remedial education component during the 1986 summer program.

TWO YEAR PLANNING

Lastly, two of the most important aspects of JTPA, at least from the point of view of their value for management improvement, are the provisions for forward funding and a two-year planning cycle. Against the backdrop of monumental problems under CETA, both of these provisions were greeted with much anticipation by the private sector volunteers and the professionals involved in the management of the program because they would make implementation of longer-term strategies possible. Unfortunately, since the passage of JTPA in 1982, annual budget uncertainties have made two-year planning a virtual impossibility. We urge you to provide as much funding stability as possible in terms of prospective funding and by permitting the system to spend already allocated dollars within the authorized time periods.

CONCLUSION

Our challenge today is to create a flexible job training system that can meet the eeds of very diverse unemployed citizens residing within our states. Just as the problems faced within our state and local economies extend beyond the boundaries of any one state, the states' ability to prepare our nation's workforce for continued economic growth is inextricably tied to and requires a sustained and substantial commitment from the federal government. While it is impossible to ignore the need for restraint in federal funding, we urge you to carefully consider support for employment and training programs.

Thank you for providing me the opportunity to present the Governors' views on FY 1987 appropriations for employment and training programs. I will be happy to answer any questions you may have.

STATEMENT OF WILLIAM L. HEARTWELL, JR., EXECUTIVE VICE PRESIDENT, INTERSTATE CONFERENCE OF EMPLOYMENT SECURITY AGENCIES

Senator WEICKER. Next, we have Mr. William Heartwell, executive vice president of the Interstate Conference of Employment Security Agencies.

Mr. HEARTWELL. Good morning, Senator.

Senator WEICKER. Good morning.

Mr. HEARTWELL. Mr. Chairman, we do appreciate this opportunity to testify, and as you probably are aware of, the Interstate Conference represents the State administrators who operate the employment service and unemployment insurance service across the Nation, all 50 States, plus Puerto Rico, the Virgin Islands, and the District of Columbia.

In the past, sir, this organization has appeared before this committee on many occasions to request additional and necessary funds for our basic programs of employment service and unemployment insurance, and also for additional help on automation and for increased nonpersonal services resources, and first we want to express our appreciation for the support that the subcommittee and the full committee has provided us in the past and particularly to members of your staff who have been most cooperative in helping us analyze some of these problems in working with the Department of Labor to increase our funding.

This year, in spite of the fact that the impact of Gramm-Rudman and other cuts have actually reduced our funding and our services that we could provide to employers and to unemployed, and in spite of the fact that we have a tremendous surplus in the "Employment security administrative" account, we are sensitive to and recognize the implications of the Budget Reduction Act of 1985, and we are committed to actually operate our programs within the limits of the President's budget, sir. In other words, we are not requesting any additional funding on our basic programs for fiscal year 1987.

I would like to point out, however, sir, that we are most hopeful that Congress will pass an appropriations bill, because we feel that if sequestration does take place in 1987, that relatively the whole system will be in a state of chaos. We base this on the fact that of a survey that we made with 32 States reporting so far, that if sequestration is in the range, say, of 20 percent in 1987, we would have to actually lay off around 6,500 total personnel and close 350 additional offices.

I don't think we would be able to maintain a viable National Labor Exchange, and also I think the integrity of the unemployment insurance system will be severely compromised.

I think, when you look back on the cuts that were made in 1982 on the employment service, when it was reduced from about 30,000 to 22,000, and then when you consider the additional cuts from Gramm-Rudman this year, plus an additional potential sequestration in 1987, you would actually see a program that has been very productive and, I think, very cost effective in the past 50 years, you would see it reduced in a period of 5 years almost 50 percent.

We do want to thank you for helping us stabilize our programs, and we would like to solicit, of course, the committee's continuing support to see that we are maintained at a level that we can provide the best services we do.

Just two other areas in which we feel the committee could be of assistance and it is very necessary for us to have more flexibility in our system. As you know, the Trade Adjustment Assistance Act was just extended until 1991 by the Congress. As a new component in the act that requires all recipients maintain a job search, we feel that the Employment Service will be designated and selected to do this. There is no administrative funding for it.

Real quickly, sir, the other assistance that can be provided is included in attachments in our testimony and in attachments to the testimony that provide the States with more flexibility which can be done administratively in the unemployment insurance system, which we have talked to members of your staff about. So we do appreciate this opportunity, sir.

PREPARED STATEMENT

Senator WEICKER. Very well. Thank you very much. I appreciate your testimony.

[The statement follows:]

STATEMENT OF WILLIAM L. HEARTWELL, JR.

Mr. Chairman, members of the Subcommittee, my name is William L. Heartwell, Jr., I am Executive Vice President of the Interstate Conference of Employment Security Agencies (ICESA), Inc. ICESA is the organization representing administrators of state unemployment compensation laws and public employment service offices throughout the country. We appreciate this opportunity to present our views concerning FY 1987 appropriations for the programs our members administer.

In the past, we have requested your support for additional staff for both employment services and unemployment insurance, for additional funds for automation, and for increased non-personal services resources. You and your staff have been diligent and helpful in investigating our arguments for these additional funds, and we appreciate the support this Subcommittee has given us over the years.

This year, we recognize the constraints placed on the FY 1987 appropriations process by the Balanced Budget and Emergency Deficit Control Act of 1985. Therefore, even though our system still badly needs funds to better serve employers and unemployed workers, and even though there is a healthy balance of federal unemployment taxes collected for this purpose, we are committed to accomplishing the basic functions of the employment security system within resources requested in the President's FY 1987 budget.

More specific comments about the major components of the employment security system are provided below:

EMPLOYMENT SERVICE

The first sequestration order, which became effective March 1, actually will impact on Employment Service operations for Program Year 1986 which runs from July 1, 1986, through June 30,

1987. ES funds were reduced by $34M, bringing Program Year 1986 funding down to $758.1M. This represents a reduction of $19.3M from our current Program Year operating level of $777.4M.

Based on a recent survey of State Employment Security Agencies, we can definitely report that as a result of losing funds there will be further reductions in service levels directly caused by the closing of offices as well as staff cuts. Information provided by 32 states to date indicate we will close 73 local offices and eliminate over 900 positions. We estimate ES staffing will drop to a level of approximately 21,500. It is important to note in this regard, that the Employment Service has already undergone severe reductions in staffing and service delivery resulting from the 1982 appropriations process. At that time we were forced to reduce ES staffing from 30,000 to 22,800 and to close 200 offices. As a result of this action we are deeply concerned over the devastating impact that another sequestration would have on the system and the diverse services it provides. We firmly believe that if a second round of cuts were effected in the range of 15-25%, states would again be faced with closing much of their operations and a viable national labor exchange would cease to exist. A reduction of this magnitude from the reports of the same 32 states previously mentioned, indicate that the system would lose an additional 3,000 ES staff and close another 350 local offices.

We also feel it is important to recognize the current services being provided by the states in the employment and training area in serving two major categories of workers that are experiencing difficulty in obtaining gainful employment in today's economy.

We are referring to youth and the dislocated worker. Of the 3.5 million persons the employment service placed into jobs, we estimate approximately 40% are youth under 22 years of age.

Regarding assistance to dislocated workers, the coordination between the employment service and the JTPA system indicates that 45 state employment security agencies have administrative and/or operational responsibilities in the Title III JTPA Dislocated Worker Program.

We mention the above only to emphasize that further cuts would seriously impair vital services in these most important areas.

We are also concerned about funding for two additional programs that are administered by our system: Trade Adjustment Assistance (TAA) and the Targeted Jobs Tax Credit (TJTC). TAA was recently reauthorized by Congress, and extension of the TJTC Program is included in both the House and Senate tax reform measures. The President's budget, however, assumes termination of both programs and provides no administrative resources.

As you know, the Trade Adjustment Assistance (TAA) Program was recently extended to 1991, as part of the FY 1986 budget reconciliation bill. A major change in the employment and training provisions mandates that recipients participate in an approved job search program. As you consider the level of funds needed for TAA, we request that you include an adequate amount for administration, including the additional resources that will be required to manage the mandated job search portion.

Another area for your consideration, concerns administrative funds for the Targeted Jobs Tax Credit (TJTC) Program. Even though the Program expired December 31, 1985, Congressional interest in extending and modifying the Program remains strong. Specifically, both the House-passed tax reform bill and the Senate Finance Committee tax reform plan include an extension of TJTC. In addition, there continues to be significant interest and support to pass a temporary extension of the Program, including a retroactive provision. Our primary concern with all of this TJTC activity is to ensure that the State Employment Service System receives adequate administrative funds to fulfill its responsibilities as the statutorily designated certifying agency.

From a recent survey of State Employment Security Agencies, we have learned that the Fiscal Year 1985 appropriation of $27.5M for TJTC administration provided less than half of the required costs. State agencies had to divert scarce Employment Service staff to keep pace with the processing requirements. Our information actually reveals that, on average, State TJTC allocations lasted only four months.

Over the past few months, employers have been contacting our agencies in unprecedented numbers, in anticipation of an extension of the TJTC Program, and particularly a provision which would make the Program retroactive to January 1, 1986. The employer's message is clear: they have continued to hire TJTC eligibles and expect the State agency to expeditiously process the requests for vouchers and certifications that will be forthcoming in large volumes immediately following the passage of an extension. Quite frankly, the states will not be able to meet this demand without adequate administrative funds.

UNEMPLOYMENT INSURANCE

The President's budget for FY 1987 would restore most of the cuts to UI that resulted from the FY 1986 Gramm-Rudman-Hollings sequestration order. Shortages of funds in areas such as non-personal services and automation would still exist at this level of funding, however, we believe that additional flexibility in the use of funds would permit us to continue to provide adequate services to unemployed workers in FY 1987.

If the sequestration process were to take effect in FY 1987, the ability of the UI System to meet its responsibilities to unemployed workers would be compromised. A survey of state employment security agencies, with 32 reporting, shows an estimated reduction in staff of about 4,500 if the cut was 20%. In addition, local offices would be closed in 350 locations in those 32 states. The effects of such a severe reduction would be so devastating that it is difficult to project just what would happen. There would likely be delays in processing claims, more erroneous payments, and fewer taxes collected.

As you know, the Department of Labor has initiated a review of administrative financing of the unemployment insurance system. Public meetings were held this past January. Both oral and written comments were solicited from all interested parties; ICESA's comments are attached for your information. The Department is continuing discussions with an advisory group made up of representatives of business, labor, states and the public.

Several of the changes which we recommended to DOL we also recommend to you because they involve changes in the language of appropriation bills that would give states greater flexibility in managing scarce resources. First is elimination of the requirement that normal budgetary adjustments be made quarterly. There is appropriation language which makes contingency funds available "only to the extent necessary ... (for certain purposes) ...which cannot be provided for by normal budgetary adjustments." The last phrase has been interpreted to require the Department of Labor to recapture any unspent funds at the end of each quarter. This has had the effect of forcing states to budget on a quarterly rather than an annual basis, restricting the ability to plan and manage resources most effectively.

Our second recommendation is that funds appropriated in one fiscal year be available for expenditure during that year and the following fiscal year. This would permit states to use any savings they were able to achieve during one fiscal year toward capital expenditures the following year.

In order to maintain our current level of services to unemployed workers within the resources requested in the President's budget, we need as much flexibility as possible in managing these resources. Therefore, we urge you to restrict application of budgetary adjustments to the end of the fiscal year and to permit appropriated funds to be spent over two years.

LABOR MARKET INFORMATION

A vital component of the Employment Security system is the Labor Market Information program which provides data to assist the Unemployment Insurance/Employment Service operation and support state/local planners in evaluating labor market conditions. As the workplace becomes more technologically advanced and the labor force more sophisticated via enhanced education efforts, information on labor market opportunities in relation to economic development will be more and more important. We will continue our efforts in further improving the major contributions we are making as labor market analysts.

In conclusion, our organization remains dedicated to improving the public programs that we offer at no charge to our clients--employers looking for workers, the unemployed in transition to reemployment, and information on this labor exchange process. Thank you for this opportunity to present our views. I will be happy to answer any questions that you may have.

The United States Work Force Served by the Employment Service (ES) Program Year 1984

- The Employment Service is clearly the principal labor exchange agency in most U.S. communities. In many towns and localities with populations under 100,000 the Employment Service is the only labor exchange entity available to employers and workers.

- It is estimated that the Employment Service obtains between 12-15 percent of the 40 percent of the total job openings actually listed in the national labor market. The remaining 60 percent are filled by word of mouth, personal contacts, direct recruitment and advertising. The Employment Service then captures about 30 to 38 percent of the share of the total available market, at a cost of only about $780 million per year.

- The new and renewal applications in the Employment Service reflected 17,741,021 transactions indicating the registration of 16,034,192 individuals.

- Of the number registered, a positive service outcome (placement in job/training) was experienced by 3,576,775 individuals. Other services were rendered to 5,933,782 persons (counseling, testing, job development) to reflect a total of some services to 9,510,557 individuals.

- Of the total placement transactions of 5,081,599, direct placement in jobs benefited 3,480,077 individuals or 68.5 percent.

- Demographically, the Employment Service placements were: 1,984,654 or 57 percent males; 1,496,048 or 43 percent females. Minorities constituted 35.4 percent of Employment Service placements (Blacks 23.7%; Hispanics 9.3%, American Indians .9%).

- Applicant groupings of Employment Service placements were:

  - Veterans - 13.7 percent
  - Displaced workers - 2.8 percent
  - Welfare - 4.6 percent
  - WIN applicants - 2.3 percent
  - Handicapped - 3.4 percent
  - U.I. claimants - 15.7 percent
  - Youth percent - 38.6

- The Employment Service provided expanded placement related services to individuals:

  - Jobs obtained from ES job search or job finding clubs - 77,083;
  - Counseling - 621,108;
  - Testing - 648,971;
  - Enrollment in training 148,376;
  - Job development contacts - 1,374,179
  - Referral to other supportive services - 1,358,539.

- The Employment Service system also provided placement assistance to other applicant groups:

  - (TJTC) Targeted Jobs Tax Credit candidates totaled 1,342,951 vouchers and 621,889 certifications;

  - (MSFW) Migrant and Seasonal Farm Worker program served 152,839 new and renewal applicants;

  - (Older Workers) Services to older workers ages (40-54), 2,152,006 and ages 55 and over, 755,942 for a total of 2,907,948.

SOURCE: USES, U.S. Department of Labor.

- (TAA) Displaced Workers - Intake and assessment 38,441, counseling services 18,065 and job referrals 12,844, referrals to training 8,668.

UNEMPLOYMENT INSURANCE ADMINISTRATIVE FINANCING REFORM COMMENTS AND RECOMMENDATIONS

INTRODUCTION

The Social Security Act of 1935 established the Unemployment Insurance (UI) system with broad federal guidelines for coverage of workers, taxation, and benefit eligibility, leaving wide discretion for state-specific program design.

In recent years federal intervention into the details of the UI system has increased significantly. At a time when federal intervention in job placement programs and other social programs has been relaxed, new federal standards for UI benefits have been enacted (e.g., pension offset, waiting week, denial of benefits to professional athletes). These standards have limited/reduced the payment of UI benefits. During the same period, there have been reductions in administrative funds and tightened fiscal controls. The apparent result of this increased federal intervention in both benefits and administrative funding has reduced benefits for many eligible claimants and has reduced the number of individuals eligible for benefits and has denied states funds to maintain quality and to prevent fraud, waste and abuse.

In looking back, it becomes clear that a significant change in the attitude toward the benefit payment side of the program developed in 1967 when the decision was made that receipts of all trust funds held by the U.S. Treasury, including those of the states' UI benefits accounts, were to be incorporated in a unified Federal budget beginning in 1968. Since that date, expenditures from these funds (UI, Social Security, etc.) have been reflected in the total national budget. Reduced expenditures from trust funds improve the national budget balance, regardless of the dedicated nature of the trust funds themselves. In the instance of UI funds, monies raised solely by the states available, solely for the payment of unemployment benefits, are treated as if they were expenditures of federal funds. These dedicated funds, including the trust funds used for administration, should be removed from federal budget totals.

In addition to concern about increased federal intervention in the program, many states are concerned that the impact of administrative funding on the trust fund--both benefit payments and tax collections--is not recognized. Certain activities more than pay for themselves in benefit savings/recoupment or in increased tax revenues. This relationship should be acknowledged in the funding process.

The following comments address issues more directly related to administrative financing reform. The underlying objective of these recommendations is reduced federal intervention in the UI program.

SHORT-TERM PROPOSALS

Short-term proposals are those than can be implemented in the FY 1987 appropriation, allocation, and contingency funding processes. The focus of these proposals is increased flexibility in the management of inadequate resources.

A. Allocation Method. Due to short time frames, only two changes are proposed for the FY 1987 allocation process.

1. Base staffing should be on the basis of the average of the four quarters, not the low quarter.

The low quarter budget methodology creates inequities in the amount of funding provided to the states. It also creates a major problem of staffing each quarter in anticipation of rising or falling seasonal claimsload.

In addition to the total direct funding, the number of base staffyears determines by formula the amount of AS&T, NPS and Support staffyears and dollars in the total base budget. States with relatively larger seasonal swings will have base staff levels well below the yearly average staff levels. Since total funding for base staffyears is greater than for above-base contingency staffyears, states with broad seasonal swings will be awarded proportionately fewer dollars than states without significant seasonal factors.

The budget methodology should be revised so that the average staff rather than low quarter staff, is the base for allocation of base budget resources. This change will improve the quality, continuity, and integrity of program and budget management.

2. Revise the UI Salary Survey to tie salary rates to future budgeted positions, rather than the survey month positions.

Each year DOL requires a salary rate survey for UI. This determines the average salary to be used in calculating the personal services requirements for the next year.

The salary rate calculated based on the survey month will be factored against the next year's budgeted level of positions, even though that budgeted position level may be far different than the survey month position level. DOL never comes back and compares the budgeted level of positions with the survey month positions, and thus can either underfund or overfund a state. The over or underfunding is a result of the change in the mix of staff, and thus the average salary rate requirement, between the survey month and the future budget.

The Department of Labor should reevaluate the salary rate survey results once the budgeted level of positions is known, and make appropriate adjustments, upon consultation with the states.

B. Financial Management and Control. Substantial changes should be made in the contingency funding process and control of UI resources by the Department of Labor for FY 1987. The changes proposed below would improve states' ability to plan and manage their resources:

1. States should be reimbursed for earned staff whether used or not and these staff earnings should not be subject to recapture.

The states, through their detailed Cost Model Studies, have demonstrated the level of funding required to perform the basic UI functions. During the budget process, these time factors have been arbitrarily cut. The states are then subjected to quarterly balancing acts in order to avoid over or underutilization of staff, with "surplus" staff resources recaptured and overspending left unfunded. There are no incentives to save staff time since such a savings will be recaptured.

The states should be allowed to retain all staff time earned, without regard to the actual usage or the quarter in which variances occurred. The resources freed from daily budget balancing could be used to increase program quality, more effectively manage the program and make productivity improvements without the fear of losing resources.

This practice would permit states flexibility in the use of resources among various budgeted staff categories. For example, staff could be moved between benefits and tax without affecting contingency funds and staff resources could be used for nonpersonal services (NPS) without penalty. This means that staff and overhead resources would be interchangeable.

2. States should permitted to use staff that are not necessary to accomplish specific functions (e.g., cost model, quality control) for other activities.

   The only concern of the Department of Labor should be whether a specific function is accomplished, not the number of staff assigned to it.

3. Eliminate the quarterly recapture of unobligated balances.

   The normal budgetary adjustment (NBA) process unduly restricts the budgetary, fiscal, and operational flexibility of the states. Ninety-five percent of budget surpluses are recaptured by DOL. States are allowed to modify their budget plans prior to the start of the quarter affected. This procedure does not protect the resources of a state when unforseen circumstances arise within a quarter.

   A more sensible approach would be to hold states harmless until the end of the year, allowing states to manage costs and staff within annual rather than quarterly timeframes. Better program management will result.

   In addition, beginning with FY 1987 funds, the appropriations language should be modificed to permit states to carryover unobligated balances from one fiscal year to the next.

4. The states' ability to absorb salary and law changes should take into consideration the total financial status of the program, not only salary rate savings.

   Before DOL will provide additional UI base funding, whether for legislatively approved salary increases or law changes, they will calculate the amount of salary rate savings a state may have accrued and reduce this amount from their request. The logic for their adjustment is that the state was overfunded in the base budget, and contingency funds (the source of the salary and law reserve) cannot be used until base resources have been exhausted.

The problem is that DOL does not look at the NPS or AS&T portions of the base budget. A state could have been underfunded by $1 million in NPS, thus the base budget has no excess resources, and yet because there may be salary rate savings, the valid salary and law reserve request is reduced or denied in total.

DOL must look at the entire UI program financial status of the particular state when considering whether a state has sufficient resources, not just rate savings.

5. Supplemental budget requests should be processed in a more timely fashion.

   Delays in the federal processing of supplemental budget requests (including any mechanism that provides federal resources to the states) place the states in an environment of uncertainty while awaiting approval or disapproval. The natural reaction is for the state to be very conservative in spending, pending all but the highest priority purchases.

   When supplemental budget request action is delayed, it may appear that the state is accumulating sufficient funds, through their conservative behavior, to offset a portion of the amount requested. The states should not be penalized for responding conservatively to funding delays, and the Department of Labor should make the review and approval of supplemental budget requess a higher priority.

C. Management Improvements. In addition to purely financial considerations, the following changes should be made that would improve federal-state relations in the management of the unemployment insurance program.

   1. Desired levels of achievement should be reduced in number and/or modified to reflect reduced resources.

   2. The Department of Labor should provide information concerning the use of all UI administrative funds, including federal administrative funds and state grants for national activities.

   3. Resources provided to states for specific purposes should have minimum broad requirements and controls, leaving detailed decisions regarding implementation to the states.

INTERMEDIATE-TERM PROPOSALS

The following proposals are recommended for FY 1988 and beyond. They address the adequacy of funding as well as improved allocation methods.

1. Involve the states in formulation of the federal budget request.

   The Departmetn of Labor should work with the states in developing the Department of Labor's budget. This input will allow for the presentation of documentation in support of mutual goals in the development of accurate levels of resources necessary to serve the public by each program area.

   The federal/state partnership can be strengthened by providing a forum for the frank discussion of budgetary issues and the exchange of ideas. Perpetuation of the current top-down approach insulates USDOL administrators and stifles creativity and mutually beneficial solutions to problems.

2. The Cost Model studied MPU's should be funded.

The rationale for MPU reductions by DOL is rooted in the budget cutting imperative. Rather than adequately finance current administrative costs and consciously guide and finance productivity improvements, MPU's are reduced to agree with federal budget targets. This arbitrary approach, fostered by a short-term savings mentality, discredits DOL's legitimate efforts to improve productivity. Unilateral productivity assessments usually result in a sacrifice of quality and not improved methods. This fact has been borne out by Random Audit studies. It undermines state faith in the federal/state partnership. It does nothing to improve cost efficiency. As long as the cost model is used, the unique state MPU's should be fully funded.

3. Nonpersonal Services requirements should be funded.

The amount of funds requested by DOL and eventually allocated to the states for UI nonpersonal services (NPS) is not sufficient to cover the actual costs of the program. This forces the states to take action that ultimately affects program quality. Staff resources that are already reduced due to the effort to match the federal appropriation are further reduced to compensate for inadequate nonpersonal services funding. The states are also forced to make reductions in variable line items of the budget (i.e., travel, communications, supplies, etc.) because a greater proportion of the budget must be utilized to cover fixed costs, such as facilities and equipment.

The allocation methodology for distributing the NPS resources to the states has not kept pace with changes occurring within the individual states, and has not resulted in an equitable distribution of the limited resources.

Despite Congressional awareness that sufficient funds for UI NPS have not been provided to the states, as evidenced through supplemental NPS funding, these additional resources have not been added to the base budget for the ensuring years.

The Department of Labor should work with the states in an effort to develop a budget request to Congress that includes adequate nonpersonal services funding so that the need for states to balance the UI budget through extraordinary means affecting program quality is eliminated. Every effort should be made to request and obtain sufficient funds during the initial budget process, rather than rely on Congress to act on supplemental funding.

The Department of Labor should also involve the states in an effort to revise the allocation methodology of distributing UI nonpersonal services resources to the states, taking into consideration unique state geographic and operational environments, rather than as an historical relation to previous year's staff.

4. Reduce the wide variances in budget and rates between base and contingency staff.

The salary rates, benefit rates, nonpersonal services, UI support and AS&T rates for contingency staff are significantly below the base budget rates. This is due to the assumption that base funded staff are permanent and all above-base contingency staff are temporary. It also assumes that basic nonpersonal services, such as facilities, have been adequately funded in the base budget and therefore contingency resources are not needed.

Neither assumption is entirely correct. Permanent staff are often utilized to process contingency workloads, costing the same as their "base" counterparts, requiring adequate facilities, supplies, and the same administrative support. Nonpersonal services shortfalls in the base are an annual occurrence. The arbitrary and inadequate above-base rates neither fund the actual cost of the contingency staff, nor compensate for underfunding in the base budget.

The Department of Labor should join with the states to reevaluate the budgetary rates for contingency financing, reducing the wide variances from base rates and more adequately financing the actual costs incurred by the states.

5. Fund the negotiated indirect cost rates for administrative overhead (AS&T).

The states prepare annual indirect cost rates. They are negotiated and approved by the USDOL Office of Cost Determination. The purpose of the indirect rate is to provide a means of budgeting for state administrative overhead (AS&T).

The Employment and Training Administration has continuously failed to recognize and fund these negotiated rates for the UI program. The amounts provided are arbitrarily derived, and often disproportionately below the amounts recovered from other federal contracts and grants. This forces the states to either reduce all administrative overhead spending to the level the UI program can afford, or else overspend the UI's AS&T budget and reduce direct program expenditures.

The Department of Labor should utilize the vehicle designed to budget for administrative overhead (i.e., the indirect cost rate in accordance with OMB Circular A-87).

6. Direct UI program management should be fully funded.

The amount of resources provided for UI support (direct management of the UI program, supervision, training, etc.) is currently based on a percentage of base direct staff with a small addition based on contingency staff. Many of the support activities do not vary directly with the workload. Indeed, these needs may increase disproportionately as a large number of untrained individuals are recruited. Closer supervison and more training are required for overseeing the work of large numbers of people unfamiliar with normal operating and procedural requirements. The current allocation methodology does not take this into account, resulting in underfunding of UI support functions. The failure to provide sufficient resources for supervision, training and the ability to oversee the activities of quickly hired temporary staff undermines the effectiveness of the entire unemployment insurance system.

The Department of Labor should work with the states to design a more logical and equitable method of justifying and allocating resources for direct UI program management.

LONG-TERM PROPOSALS

Proposals for major changes in the administrative financing of the Employment Security System continue to be debated. There is a concern that the accumulation of excessive amounts in the Employment Security Administration Account should not continue. Funds collected for administration of the Employment Security System and needed by the states should be made available. Mechanisms for accomplishing this objective should be addressed jointly by the states and the Department of Labor.

STATEMENT OF JAMES R. FORNEAR, CHAIRMAN OF THE BOARD OF RES-CARE, INC.

Senator WEICKER. Our next witness is Mr. James Fornear, chairman of the Board of Res-Care, Inc.

Senator WEICKER. Mr. Fornear?

Mr. FORNEAR. Mr. Chairman, I am honored to have the opportunity to appear in support of adequate funding for the Job Corps Program. It is my pleasure to present this statement on behalf of many business, labor and voluntary organizations associated with Job Corps. The Job Corps survived for over two decades by building a program which earned the strong, bipartisan support of Congress. It is ironic that now that the center, that the programs are so effective, we must fight harder than ever to avoid center closing spurred by a philosophy of across-the-board budget cutting.

As time is limited, I will let the Job Corps numbers speak for themselves. According to the Labor Department's statistics, during the first half of the program year of 1985, Job Corps produced a rate of positive outcomes of 81.3 percent. Of this total percentage, 66.1 percent found unsubsidized employment, and 15.2 percent graduated to further education or advanced training.

Standing alone, these results are impressive enough, when you consider this success was achieved with youth who were anything but job ready. I think the results are nothing short of incredible. Our opponents say the cost is too high. Well, the average cost per trainee in 1984, including room and board, medical, dental assistance, and even capital improvements, was $6,172. the mathematical study indicates the Job Corps returns $1.46 cents for every $1 invested in the program, through increased taxes, reduced income maintenance payments, and reductions in crime.

Additional independent reviews completed more recently by the National Research Council and others have consistently upheld the accuracy of the mathematical study. So what is to become of Job Corps? Mr. Chairman, you and the members of the subcommittee, and Congress as a whole, are to be commended for thus far refusing to allow the closing of any centers. However, with the 4.3 percent fiscal year 1986 automatic reduction under the Gramm-Rudman-Hollings Act that is scheduled to go into effect on July 1, we, again, confront possible center closings.

The logic which guided Congress from closing centers last year is no less compelling now. As a means of avoiding otherwise inevitable center closings on July 1, we suggest three alternative approaches to the fiscal year funding problem: the first and most desirable is to restore the 4.3-percent cut for this fiscal year through a supplemental appropriation of $27.5 million. This amount would simply return the program to the current services level, which was adopted by Congress last year.

We believe the Job Corps record justifies this approach. A second and somewhat less desirable approach would be to enact a smaller fiscal year supplemental appropriation of $17.5 million. At this level, it is estimated no centers would be required to close, because we project a one-time overhead savings amounting to approximately $10 million. The third and least attractive alternative would require no supplemental appropriation but would represent a setback in our efforts to make needed facility improvements.

This approach requires directing the Labor Department to use, for programmatic purposes, approximately $17 million of 1986 funds. The Job Corps community is virtually unanimous in support of the $27.5 million supplemental appropriation. We would prefer, of course, any of these alternatives to center closings.

We urge you to adopt these options before July 1. Otherwise, center closings will become a reality, and congressional discretion would be lost. With respect to 1987, Mr. Chairman, there is no reasonable alternative to providing at least the current services level, approximately $167 million. This funding level would provide training for over 100,000 annually and require no center closings or disruptions of services to disadvantaged youths.

I have had a lot of opportunities to congratulate young people graduating from the Job Corps. They have accomplished their transition from tax burdens to tax producers. I urge you to recognize them by continuing this program. It is certainly within your power to honor them in the only way which really matters, by refusing to close even one center now or in the future.

Thank you.

Senator WEICKER. Thank you very much. I don't think there is any question that the Job Corps has the support of this Senator and indeed the U.S. Senate. To speculate on the fact that we are going to be able to restore the automatic Gramm-Rudman cut in the supplemental, that isn't going to happen. It just will not happen. If that were the case, there would be 100 other agencies in here seeking to restore the automatic cut.

As I explained at the outset, when I was one of the handful to vote against Gramm-Rudman, it is for the very reasons that you cite: that that is a bad piece of legislation. It is not in any way sympathizing with what occurred. Indeed, I opposed it as best I could. Now we are stuck with it, and at least insofar as the automatic aspect of 1986 is concerned, I think there is little that can be done about it.

As far as 1987 is concerned, that is why you are here. The American public should clearly understand there is nothing automatic about Gramm-Rudman from 1987 on, assuming it is constitutional.

There is nothing automatic. What the American people want, their priorities in their budget, they are going to get. What they don't want they are not going to get. If Job Corps is important, then they ought to speak out on it and they ought to make sure their representatives hear that story, and it is a fine story, it is a fine story, so that the Job Corps will not be affected in fiscal year 1987 as it is going to be affected in fiscal year 1986.

PREPARED STATEMENT

Mr. HEARTWELL. There are some alternatives, as I said, to those closings, and we appreciate your looking at them.

Senator WEICKER. Fine, thank you very much. Thank you.

[The statement follows:]

STATEMENT OF JAMES R. FORNEAR

Mr. Chairman and Distinguished Members of this Subcommittee, my name is James R. Fornear and I am Chairman of the Board of Res-Care, Inc., a company headquartered in Louisville, Kentucky, which provides residential training for both the economically and the developmentally disadvantaged.

I am honored to have the opportunity to appear before you in support of adequate funding for the Job Corps program, our Nation's most successful, cost-effective and enduring Federal training program for hardcore unemployed youth. It is my pleasure to present this statement on behalf of many business, labor and voluntary organizations associated with Job Corps. A complete listing of organizations supporting the Job Corps program is attached at the end of my statement.

I intend to present the case today against closing Job Corps centers on the theory that such action will reduce the Federal deficit--a theory which all dependable evidence proves to be tragically short-sighted. But before I proceed, Senators, I think I should give you a brief history of both my and my company's involvement with Job Corps.

My roots in Job Corps date back to the birth of the program in 1965. In that year, I started as Director of Activities and Development for what was then the Breckenridge Job Corps Center--now known as the Earle C. Clements Center--located in Morganfield, Kentucky, which was among the first and largest of the initial centers established. At that time, the Center was operated by Southern Illinois University under contract with the old Office of Economic Opportunity. Later that year, I became Acting Center Director at Breckenridge.

In 1966, the Singer Company took over the operation of the Breckenridge Center, and I was asked to stay on as Center Director, a position which I held through 1967 and, again, from 1969 until 1976. In 1976, I joined Res-Care in the dual capacity of Company President and Center Director of the Whitney M. Young Job Corps Center in Simpsonville, Kentucky. In 1984, I became Chairman of the Board of Res-Care, Inc.

Our company currently operates five Job Corps Centers under contract with the U.S. Department of Labor, including the Atterbury Center in Indiana, the Gulfport and Mississippi Centers in Mississippi, the Joliet Center in Illinois, and the Miami Center in Florida. Also, we presently operate the academic program at the Frenchburg Civilian Conservation Center in Frenchburg, Kentucky, under contract with the U.S. Department of Agriculture's Forest Service.

Mr. Chairman, Job Corps has struggled for many years to become the unique and successful program it is today. Through experimentation and innovation, Job Corps was able to capitalize on its initial mistakes. Our early failures taught us that conventional approaches to education and training by and large were ineffective with the Job Corps population, and that to succeed, Job Corps would have to build its own model for residential, open-entry/open-exit, vocational and academic training. Through hard and determined effort, the program has been able to accomplish this objective.

The Job Corps has survived for over two decades, during which time it has earned the well-deserved respect of the American public as well as strong bipartisan support here in Congress, precisely because it has climbed so far from its difficult beginnings. It is sadly ironic that now, as Job Corps nears the summit, we must fight harder than ever to justify the program's continuation and to avoid center closings spurred on by a philosophy of across-the-board deficit reduction.

I could spend hours telling you of the thousands of young lives which I personally have seen diverted from welfare dependency and jail cells to productive self-reliance through Job Corps participation. For example, I could tell you about several of my former Corpsmembers who since their graduation from the program have gone on to become lawyers and PhD's. Or I could recount the story of a man I know in Louisville, who while expressing his appreciation recently for the chance to "make it" which Job Corps gave him, told me that the two auto-body shops he now owns and operates provide him with an annual income in excess of $60,000.

However, as time here is limited, I must let the Job Corps "numbers" speak for themselves. In fact, current program and participant data tell the story of the quantum leap forward made by Job Corps since 1965 far more eloquently than I could.

According to actual Labor Department data sources, during the first half of Program Year 1985 (the most recent period for which complete data is available) Job Corps produced a rate of positive outcomes of 81.3%. Of this total percentage, 66.1% represents the number of participants who found unsubsidized employment, the vast majority of these in the private sector, and 15.2% represents the number of participants who left the Job Corps for further education or advanced training. Standing alone, these results are impressive enough. However, when you consider the additional fact that this rate of success was achieved with youth who were anything but job-ready, these results become nothing short of incredible.

The typical Job Corps enrollee during the first half of Program Year 1985 was an economically disadvantaged, 18-year-old high school dropout, who was a member of a minority, read at or below the sixth grade level at program entry, was never employed full-time, and came from a family receiving either public assistance or $6,064 in annual income. Specifically, Job Corps enrollees for that period were 58.8% black, 26.1% white, 9% Hispanic, and 6.1% came from other groups. Approximately 26.7% of enrollees read below the fourth grade level, and a full 80% of all enrollees read at or below the eighth grade level when they entered the program. 75% of all participants had never been employed full-time. 40% came from families receiving public assistance, 46.6% came from families with annual incomes of under $5,000, and 70% of all Corpsmembers came from families with incomes of under $9,000 per year. Roughly 40% of all new enrollees during the first half of Program Year 1985 had prior arrest records.

In view of the participant characteristics just cited, I submit that the fact that over 4/5 of these youngsters successfully complete Job Corps training, with 2/3 of them being placed in unsubsidized employment, is genuinely phenomenal.

Mr. Chairman, we hear much from those who would cut Job Corps funding about the high cost of this residential training program. Opponents say over and over that the F.Y. 1984 service year cost of $15,000--that is, the amount necessary to fund one Job Corps slot for an entire year--is too high. In fact, the more relevant figure is not the service year cost, since each Job Corps slot serves more than one participant each year, but the cost per participant, which in FY 1984 amounted to $6,172. This latter figure includes not only the average cost of training one participant, but also the per capita costs of room and board, medical and dental assistance, and the program's capital expenditures, among other items.

Furthermore, even at a time when reducing the deficit is absolutely essential, the viability of the Job Corps or any program should not be determined on the basis of cost alone, but only upon careful review of the benefits produced by the program as compared to its cost. For example, no one seriously suggests that we could save billions and reduce the deficit by eliminating the IRS.

From the perspective of cost/benefit analysis, few if any Federal programs have undergone more rigorous and exhaustive analysis recently than the Job Corps. Study after study has demonstrated clearly that the program's return on investment to American taxpayers--in cold, hard dollars--has greatly exceeded its costs. The most widely-known and highly-respected of these studies, one completed during the late 1970's and early 1980's for the U.S. Department of Labor by Mathematica Policy Research, Inc., indicates that the Job Corps returns $1.46 for every $1.00 invested in the program, through increased taxes, reduced income maintenance payments, and reductions in crime. It is well known that during 1982-83, the Labor Department conducted a review of the Mathematica Study to determine its validity, and the results of that review strongly corroborated Mathematica's results. Similarly, additional independent reviews of the Mathematica Study completed more recently by such entities as the National Research Council, the National Council on Employment Policy, the Brookings Institution, Brandeis University, and the Urban Institute have consistently upheld the validity and accuracy of the Mathematica Study results regarding Job Corps' return on investment. For the record, I have attached at the end of my statement excerpts from testimony given last May 23 before the House Government Operations Subcommittee on Employment and Housing concerning these Job Corps cost/benefit studies.

The bottom line is that for the typical American taxpayer responsible for Federal, State and local taxes, every dollar spent on Job Corps is an investment which produces a return of $1.46, with a maturation (pay-back) period of roughly three years. With respect to its impact on the Federal deficit alone, these studies demonstrate that Job Corps spending is virtually deficit-neutral by the end of this three year pay-back period. As far as I'm concerned, this means that the Job Corps is an excellent investment. It also means that closing Job Corps Centers to achieve deficit reduction is nothing more than cutting off our noses to spite our faces.

Having reviewed Job Corps' past and present, we come now to the real question confronting this Subcommittee today--what is to become of Job Corps in the future? To a large extent, Gentlemen, the answer to this question is in your hands.

While I could make a very powerful argument for increasing Job Corps funding tenfold, I realize that in reality, such testimony would be useless to you. What I can do to assist you, hopefully, is to discuss what will happen to Job Corps in F.Y. 1986 and 1987 at various funding levels, and perhaps even to suggest some viable alternatives to closing Job Corps Centers in F.Y. 1986 in order to meet the requirements of the Gramm-Rudman-Hollings legislation.

With respect to F.Y. 1986, as you know, regular Job Corps appropriations originally totalled $640 million. This sum represented continued funding for the program at its projected F.Y. 1986 current services level, allowing the program to continue at status quo. In this regard, Mr. Chairman, you, the Members of this Subcommittee, and Congress as a whole are to be commended for providing F.Y. 1986 Job Corps funding at this level rather than at the F.Y. 1985 actual appropriations level of $617 million, thereby refusing to allow the closing of any centers.

However, with the 4.3% F.Y. 1986 automatic funding reduction required under the Gramm-Rudman-Hollings Act scheduled to effect Job Corps on July 1, 1986, we again confront the immediate closing of numerous Job Corps Centers. In fact, this 4.3% "sequestration" reduces F.Y. 1986 Job Corps appropriations to the level of $612.5 million--$4.5 million below the actual F.Y. 1985 level--thus requiring the closing of between two and eight centers (depending on the size of the centers selected for termination).

Sequestration orders notwithstanding, the rationale which guided Congress away from closing Job Corps Centers last year is no less compelling now. The mere enactment of the

Gramm-Rudman-Hollings Act did not magically diminish the importance and effectiveness of, nor the urgent need for, the Job Corps.

Mr. Chairman, I believe strongly that we as a Nation must not jeopardize our present and future competitiveness in the world economy by failing to invest adequately in our human resources. In this regard, it greatly distresses all of us in the Job Corps community that serious proposals are made to cut Federal funds across the board for virtually all education, training and rehabilitation programs. Along with Job Corps, these programs are all vital parts of a comprehensive approach to maintaining a skilled, competitive workforce.

However, I must also point out that the impact of reducing funds for Job Corps is much more permanent and irreversible than is the case with the majority of other Federal programs. In the typical case involving formula-allocated Federal programs, a 4.3% reduction can be accommodated in most instances not by the permanent closure of facilities, but by a phased reduction in the number of participants, generally through some attrition technique. In the event funding is subsequently restored or increased, such programs can easily increase participation once again. But in the case of Job Corps, the Labor Department insists that a 4.3% reduction necessitates permanent center closings. History teaches us that once a Job Corps Center closes, it never reopens and, more importantly, experienced and expert staff exit the program, never to return. It becomes a very expensive proposition indeed to open new Job Corps centers and to recruit and train new Job Corps staff.

Therefore, as a means of avoiding the otherwise inevitable center closings which will occur this July 1, I would like to suggest for your consideration several alternative approaches to the F.Y. 1986 funding problem. From the point of view of the Job Corps community, the first and most desirable means of restoring the 4.3% cut for this fiscal year is an F.Y. 1986 supplemental appropriation of $27.5 million. This amount would simply return the program to the current services level for F.Y. 1986 adopted last year by Congress. We firmly believe that the Job Corps success rate and cost/benefit ratio overwhelmingly justify this approach.

A second and somewhat less desirable approach would be to enact a smaller F.Y. 1986 supplemental appropriation for Job Corps of $17.5 million. At this level, it is estimated that no centers would be required to close, because we project that there are one-time overhead savings which could be made this year which amount to approximately $10 million.

The third and, in my view, least attractive alternative which I offer for your consideration would require no supplemental appropriations, but would represent a significant set-back in our efforts to make sorely-needed capital improvements to Job Corps facilities. This approach involves directing the Labor Department to delay temporarily certain capital improvements and to use for programmatic purposes instead approximately $17 million of the F.Y. 1986 funds now budgeted by DOL for capital needs. In combination with the estimated $10 million in one-time overhead savings which I mentioned previously, this would avert the necessity for Center closings.

While the Job Corps community is virtually unanimous in its support of the first alternative--restoring the full 4.3% cut through a supplemental appropriation--we would prefer any of these alternatives to center closings. In this regard, we urge you to adopt one of these options before July 1; otherwise, center closings will become a permanent reality, and Congressional discretion, as a practical matter, will be lost.

The proponents of Job Corps disagree with those who suggest that the program overall would be better off if a few centers performing on a substandard basis were closed. We view this argument as analogous to a proposition that the last few athletes to make the Olympic team should be cut as subpar performers. In neither case does the rationale appropriately consider the fact that although the ranking of any group of exemplary performers will produce a scale on which some will fall below average, even the performance of those at the bottom of such a scale would far exceed the mean for the general population, were a broader comparison drawn. The point is not to close those Job Corps Centers which demonstrate subpar performance, because we know beyond dispute that the Job Corps model itself is extremely effective. To the contrary, unacceptably low Job Corps center performance should be corrected through proper program administration, not through center terminations.

In regard to Job Corps appropriations for Fiscal Year 1987, our position remains constant: sufficient funds should be appropriated to allow the program to operate without the disruption and unavoidable loss of capacity caused by the closing of centers. This would require a F.Y. 1987 current service level of $665.6 million, which is calculated on the basis of the original F.Y. 1986 appropriations level of $640 million. At this level, the program next year could entertain no expansion. It would permit only the continued operation of all existing centers at the current level of approximately 40,500 service years, enabling the program to serve its present level of roughly 100,000 participants again next year.

Mr. Chairman, there is no reasonable alternative to the F.Y. 1987 current service level of $665.6 million. A freeze next year at the existing post-Gramm-Rudman level of $612.5 million as anticipated in the First Budget Resolution reported recently by the Senate Budget Committee would mean the closing of an additional six to ten centers, a decrease of approximately

3,144 service years and a reduction of approximately 8,000 in the number of youth who could be served next year. Even if F.Y. 1987 appropriations were frozen at the original F.Y. 1986 current services level of $640 million, it is estimated that three to seven centers would be required to close, the service year total would be reduced by roughly 1,350, and approximately 4,000 fewer of America's poorest and hardest-to-employ youth would be served.

Job Corps proponents submit that while the passage of the Gramm-Rudman-Hollings Act may have altered decision-making here on Capitol Hill, it has in no way diminished the effectiveness of the Job Corps (as yet), nor reduced the level of youth unemployment, nor changed the fact that Job Corps is deficit-neutral. Therefore, the least that can and must be done is to maintain the program at its current services level established prior to Gramm-Rudman, so that youth now participating are not abandoned and the existing level of training opportunities is preserved.

Mr. Chairman, as I indicated earlier, I've come a long way with the Job Corps over the past two decades. As Board Chairman of Res-Care, several times each year I congratulate groups of young men and women who are graduating from the Job Corps, eager to pursue self-sustaining careers in carpentry, word processing, welding, food preparation, plumbing, nursing and other vocations. At such times, I have the good fortune to honor these youngsters and the program itself for accomplishing their transition from hopelessness to self-esteem, and from tax burdens to tax producers. Mr. Chairman and Members of this Subcommittee, I urge you to join with me in recognizing these young people and the program which gives them the chance to lift themselves up by their own bootstraps. It is within your power to honor them in the only tangible way which really matters--by refusing to permit the doors of even one Job Corps Center to be closed, now or in the future.

The following business, labor and volunteer organizations are committed to the Job Corps and seek continued full funding for this program during fiscal year 1986 and fiscal year 1987: Home Builders Institute; RCA; Singer; Teledyne; ITT; Management and Training Corporation; Coyne American Institute; Texas Education Foundation; Res-Care, Inc.; Training Management Resources; YWCA of Los Angeles; SER-Jobs for Progress; Intelcom Services, Inc.; Women in Community Service; MINACT, Inc.; Joint Action Community Service; Vinnell Corporation; Grand Rapids Public Schools; Tuskegee Institute; Training and Development Corporation; Aurora Associates, Inc.; Wachenhut Services, Inc.; Leo A. Daly; Alpha Kappa Alpha; AFL-CIO International Brotherhood of Painters and Allied Trades; AFL-CIO International Union of Operating Engineers; AFL-CIO Appalachian Council; AFL-CIO United Auto Workers; United Brotherhood of Carpenters and Joiners; National Maritime Union - Treasure Island Job Corps; International Masonry Institute; National Plastering Industry's Joint Apprenticeship Trust Fund; Brotherhood of Railway and Airline Clerks (AFL-CIO); Commonwealth of Puerto Rico; Cherokee Nation of Oklahoma; University of Nevada-Reno; Pacific Education Foundation; Tribal Council of the Confederated Salish and Hootenai Tribes of the Flathead Indian Reservation.

STATEMENT OF DENNIS K. RHOADES, DIRECTOR FOR ECONOMICS, THE AMERICAN LEGION

Senator WEICKER. Next we have Dennis Rhoades, director for economics for the American Legion.

Mr. RHOADES. Thank you, Mr. Chairman.

The American Legion appreciates the opportunity to be here and discuss the veterans programs within the Department of Labor. As I am sure you are well aware, the Department of Labor is responsible for all the employment and employment training activities within the curve for veterans in the United States. That is not really a Veterans Administration function, so funding and the mechanics of these programs within the Department of Labor is very important to the needs of our disabled Vietnam and recently separated veterans, in particular.

I might add, parenthetically, Mr. Chairman, the Small Business Administration is a part of the employment equation, and we are very grateful for your efforts to maintain the integrity of the Small Business Administration, because 27 percent of the loans now being offered are given to veterans. We think it is a good program.

Looking at the Department of Labor, we are generally pleased with the proposed budget for veterans programs. We think in light of budget realities, it is probably as good as we can do, in particular, with the Employment Service.

We are glad to see that major cuts didn't come out of the Employment Service, because the Employment Service really is the foundation of the Federal Government's veterans employment effort.

So we hope that the committee will continue to look with caution on cuts in the Employment Service, because they are ultimately going to affect veterans more than any other particular group because we are dependent on it. We are also glad to note that what little moneys there are under the Job Training Partnership Act for veterans have been increased by about 20 percent this year.

But we still find it a real disservice to our Nation's veterans that out of a $3.5 billion program, what we end up having for veterans services is a little over $10 million.

I mention that because it bears upon the consideration of funding for the Veterans and Job Training Act, which is currently being cut in the 1986 supplemental. I would like to touch on that in a moment, Mr. Chairman.

I guess our real objection in the administration's budget is the fact that funding for the local veterans employment representatives within the Employment Service is being cut about 25 percent, from its 1985 level. This program, Mr. Chairman, is very old. It was established in law by the Government issue bill in 1944. It is working very well for veterans. We would like to see it maintained, and we think that cutting these positions by 25 percent is going to do a real disservice to the veterans being helped through the Public Employment Service.

I mentioned, Mr. Chairman, that the American Legion is very concerned about the Veterans Job Training Act. It is technically not under the purview of this subcommittee, although it is a jobs program, and of course, the reason is that the Veterans Administration serves as the conduit of moneys to be paid to the employer. It is our understanding the Appropriations Committee in the House has approved the programming of $35 million in minor construction funds for 1986 from the Veterans Administration budget into this program.

But there is opposition among some of your colleagues because the program apparently hasn't used the money it has had. Well, unfortunately, Mr. Chairman, that is kind of a catch 22, because there are about $16 million remaining in the program. If the Public Employment Service were to gear up, what it is in danger of doing is promising employers something it can't deliver, and that is training funds.

So we urge you and your colleagues to take another look at that.

In conclusion, Mr. Chairman, I want to state that the legion also supports, strongly supports continuation of the President's Committee on Employment of the Handicapped [PCEH]. We, as an organization, are members of the Committee on Disabled Veterans. We have found that committee to do a great service for disabled vets, and we think it is absolutely vital, particularly in light of the recent Bureau of Labor Statistics study which showed that so many disabled vets are not even in the labor force because of attitudes toward getting a job and prejudice against them in the job.

So we went to say we are supportive and we thank you for the opportunity to be here.

Senator WEICKER. On the last point you raised, it is not a question of support by this committee or, more particularly, by this chairman, of efforts on behalf of disabled Americans, veterans, and otherwise. Indeed, I think the record pretty much speaks for itself, both in terms of authorizing legislation and of funding. Probably nobody has taken it more on their shoulders than I have.

But having said that, and living with the statistics that we have vis-a-vis disabled persons in this country, including veterans, that we have a massive population of some 27 million, two-thirds of which are unemployed, it is a higher statistic than any group, blacks, Hispanics; I don't care what you are talking about. Nothing is higher than that. Two-thirds of them want to work, want to work by the survey.

Where do you think all that come from? It didn't come from the President's Commission on the Employment of the Handicapped. It came from the National Council on the Handicapped. What I want to do, very frankly, is to move away from the cocktail parties and the splash and one thing and another that has been the President's Commission of the Employment of the Handicapped and get to the business of doing something for the disabled.

So make no mistake about it, it isn't a question of dedication. It is a question of the fact that what I feel once Congress, and you ought to be enormously pleased by this, put into law—don't forget the Presidential Commission on the Employment of the Handicapped is an Executive order—Congress by law now has the National Committee on the Handicapped. They are there by law.

When they come forth with their studies and their recommendations, as they have, believe me, anybody is going to be hard pressed to ignore them. I am saying to you that fortunately, times have changed where we no longer just have the Executive order which can be here today and gone tomorrow. We have this in the law now, which can go ahead and help. So in a time of budget crisis, or indeed any time, it is just a matter of good Government.

I want to go ahead and get these two organizations together so that we are all going down the road together and not just ad hoc efforts in one area and more efforts in another.

Please don't feel that in any way is there a diminution of the efforts on behalf of disabled veterans being your particular responsibility. Nobody feels that responsibility more keenly than I do. I might add, unlike my friends in the administration, I also feel that I am willing to put the money, not my money, everybody's money, where my mouth is. If that means taxes, it means taxes.

It should be absolutely appalling for anybody to know that under the administration's budget, 86,000 young adults are not going to receive vocational rehabilitation training, 86,000. Now tell me where we have saved any money in something like that where 86,000 aren't going to get the skills to enable them to work and to be taxpayers.

Do you think you have saved any money in that little budget maneuver? I am not talking about you, I am using the editorial "you." I am willing to carry that fight and am carrying that fight.

I think there are really two issues here. One is the President's Committee on the Employment of the Handicapped, and let me say one thing. I don't blame you in the sense that for such a long period of time this was the only vehicle. Times are changing. Thank God. I just want to make sure we change with them.

Mr. RHOADES. We appreciate your comments, Mr. Chairman, about the disabled and your support for jobs programs, because I agree with you. They are not really expenditures as much as they are investments, if they are properly run. We appreciate the help you have given us.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. We will include your statement in its entirety in the record.

[The statement follows:]

STATEMENT OF DENNIS K. RHOADES

Mr. Chairman, The American Legion appreciates the opportunity to appear before the subcommittee today to discuss the funding for veterans employment programs within the Department of Labor. Although they are often not accorded as high a profile as other veterans services, job services are no less vital to the readjustment and restoration of veterans to civilian life. Moreover, employment and training opportunities are an integral part of the social contract our Nation has made with its former soldiers, and deserve the same attention and care which the Congress has accorded to other services, such as veterans health care, home loans, rehabilitation and compensation for service-connected disabilities.

Unfortunately, this has very often not been the case in recent years. For most of the public, including veterans, services for veterans have been almost exclusively identified with the Veterans Administration. While the VA provides many services to veterans, two major (and important) service areas are not within its purview: employment and small business assistance. Except for disabled veterans vocational rehabilitation, and a moribund on-the-job training program, job and job training assistance for our veterans has been vested by Congress with the Labor Department, which is why we are appearing here before this subcommittee today.

Parenthetically, I think it is worth observing that small business generation is an important part of the job placement equation. In that regard, Mr. Chairman, The American Legion would like to express publicly our gratitude and support for your efforts to forestall the dismantling of the Small Business Administration, which has been the target of the Administration for the last several years. As you are aware, nearly 80% of all new jobs in the United States are being created by small business. Fully 27% of all SBA business loan guarantees have been made to veterans this last year. Not only does this impact the ability of an entire generation of Vietnam-era veterans to realize the American dream of private entrepreneurship, but also generates thousands of new employment opportunities for their fellow veterans.

In contrast with the imminent peril in which small business assistance now finds itself, Mr. Chairman, we are pleased to report to you today the Administration's proposed budget for the basic veterans program functions at the Department of Labor, with two exceptions, appears adequate for the Department to carry out its legislatively mandated responsibilities. We congratulate Secretary Brock and Assistant Secretary Don Shasteen for their commitment to veterans and wise management of program funds. In our estimation greater funding should be provided to State Employment Security Agencies in order for them to function as an effective labor exchange. In the context of the present deficit problem, however, it appears as if the proposed FY 1987 budget provides sufficient funding to maintain the integrity of the Job Service. We note this with the caution, however, that any future adverse changes in funding for the public employment service will have a profound effect upon the Federal government's efforts to assist jobless veterans. State Employment Security Agencies are the keystone of veterans employment programs, and it is impossible to alter the former with out affecting the latter.

We are particularly gratified to note that funding for the Job Training Partnership Act (JTPA), Title IV(c) will be increased under this proposed budget. In that regard, Mr. Chairman, we would like to point out that the Administration, in February of this year, attempted to impose a $576,000 rescission on the 1986 budget for the program, in addition to the 4.3%, or $416.000 rescission required by Gramm-Rudman. Early last month, we wrote the subcommittee, advising against approving that new rescission, since the Administration offered no justification for the reduction. Since The American Legion has not yet had a response to our letter, we reiterate our request that the Congress not approve the proposed reduction in FY 86 funding. In addition, although a $1.8 million increase in Title IV(c) funding in FY 87 is a positive step for veterans, it pales into insignificance when compared to JTPA's $3.4 billion in resources. We urge the subcommittee to provide an additional $50 million for Title IV(c).

The second proposal in the Administration's budget which the Legion finds unacceptable is the line item for Local Veterans Employment Representatives (LVERs). The FY 1987 budget proposes to reduce the number of funded positions by 275 from its FY 1985 level, and 125 positions under the FY 1986 Gramm-Rudman level. Although the Administration claims that this reduction is owing to a change in regulations which eliminates consideration of local office veteran population in determining whether there is a need for a fulltime LVER and, instead, depends solely on local Job Service office activity, the reasoning in the Administration's budget submission is perhaps more enlightening: "The number of LVERs, " the document says, "is determined by the amount available (emphasis added), divided by the FY 1987 average cost per staff year." What this is telling us, Mr. Chairman, is that, in this top-down process, need for services was nowhere considered in the Administration's budget, despite the fact that the law (38 USC 2004) is very explicit about need as the single determining factor in the fulltime status of these positions. Even if one were to accept the ostensible reason for these reductions, the single criterion of local office activity is, by its very nature, regressive, and will discourage many local office managers experiencing staff cuts in other areas to permit Disabled Veterans Outreach Program (DVOP) and LVER staff to conduct the outreach required by law. The regulations reward offices with minimal contact with the veterans community by allowing them to assign LVERs to other, non-veteran duties. We urge the subcommittee to reject this proposal for an arbitrary and capricious reduction, and to insist that the Department of Labor rely on need as the only criterion for these positions and the requisite funding involved.

Although not under the purview of this subcommittee, of principal concern to The American Legion is the fate of the Veterans Job Training Act (VJTA) which the Congress passed late last year. We note that the VA's budget for FY 1987, as well as for a FY 1986 supplemental, does not include the $65 million authorized under the new legislation for the conduct of the program. This comes as no surprise, since 1987 will mark the fourth successive fiscal year in which OMB has attempted to bury this program through lack of funding. We have spoken on a number of occasions of the chronic structural unemployment problems experienced by Vietnam-era veterans, and the same conditions exist today as those which prompted the Congress to pass this legislation, in the face of Gramm-Rudman, two months ago. The Appropriations Committee in the House has approved the reprogramming of $35 million within the VA to operate VJTA for the remainder of FY 1986, and has indicated that an additional $30 million will be appropriated for the program in FY 1987. We urge the Senate to follow suit. We trust that both houses of Congress will honor their commitment to unemployed and underemployed Vietnam-era veterans by assuring that adequate funding is provided to carry out the program as Congress intended. With less than $17 million remaining in carry-over funds for VJTA, we urge swift action to guarantee the uninterrupted conduct of the program.

Mr. Chairman, on behalf of the nearly three million members of the American Legion, may I say that we are pleased to have the chance to share with you our views on the matters under consideration today. We would be happy to answer any questions.

STATEMENT OF WILLIAM T. PATRICK, TREASURER, NATIONAL CAUCUS AND CENTER ON BLACK AGED

Senator WEICKER. Next we have Mr. William Patrick of the National Caucus and Center on Black Aged. Mr. Patrick.

Mr. PATRICK. Good morning, Senator, and thank you very much for providing this opportunity for the National Caucus and Center on Black Aged to present testimony. The report that we have already handed in covers two points having to do with the Older Americans Act, title V, the senior community services employment programs and the other senior programs that are administered by the Administration on Aging.

The effort is made in our paper to ask that current funding be maintained, consistent with what we are hearing this morning.

That is our position. If I just might make a personal point for just a moment, I have just recently become a retiree myself, having worked for a number of years up in New York City for one of those little companies just a stone's throw from the sovereign State of Connecticut. My company afforded me the opportunity for the last 5 or 6 years to work with the National Caucus and Center on Black Aged, and I have continued to work is a volunteer with that organization.

I had a personal experience in viewing the Senior Employment Program, and the program I just think is just utterly magnificent in terms of, No. 1, providing the wherewithal for living for people; No. 2, a sense of community service to people, and more important than that is a sense of self-esteem, a sense of dignity, and a sense of participation.

On that basis, we would hope that this program can be maintained. Thank you, sir.

Senator WEICKER. These programs, what did they come in at under the administration budget, the ones you are testifying on?

Mr. PATRICK. They come at the past level.

Senator WEICKER. The 1985 level.

Mr. PATRICK. With the sequestration coming in, and the only one that was cut was the title IV, the training and the research.

Senator WEICKER. At what, the 1985 level?

Mr. PATRICK. Yes.

Senator WEICKER. The 1985 level. It restores the sequestering. So it is at the 1986 level.

I want to say something in this area of the elderly. Nothing could be clearer in terms of, in this case, I gather it is once again level funding, which I suppose in light of the cuts we are all supposed to be grateful for, but across the board, it also points up one of the great failings of Gramm-Rudman: all the politicians, you see, to send a message to the elderly of the United States are saying: We are going to exempt Social Security. You are OK, we are going to exempt Social Security.

Let me tell you, in all the budgets I have responsibility for, this is fortunate, the level funding you refer to. In the case of the National Institutes on the Aging, cut; in the case of geriatric training at the medical schools, cut. I don't have responsibility for housing, but I can assure you, housing for the elderly, cut.

So I hope that there is a message that is going out there, which is if, indeed, the definition of being OK is that you pick up your Social Security check, even though you are in lousy health and don't have a roof over your head, fine, let people swallow that hook, line, and sinker. But this is a devastating budget as far as the elderly are concerned, regardless of the exemption, and a hell of a price to pay for the exemption.

When I get to be 65, thank you very much, I hope to have my health and to have a roof over my head. These are a little bit important too, in addition to the Social Security check. In the case of the aging, I think their view might have been deflected by the true status of their condition, just by Congress saying we are going to exempt Social Security. That is what worries me.

Mr. PATRICK. Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you. Your statement in its entirety will be included in the record at this point.

[The statement follows:]

STATEMENT OF WILLIAM T. PATRICK, JR.

Mr. Chairman and Members of the Labor-HHS-Education Appropriations Subcommittee, the National Caucus and Center on Black Aged appreciates the opportunity to testify at your hearing on funding for aging services activities. We fully recognize that your time is limited. Consequently, we shall keep our remarks brief.

NCBA's testimony will concentrate primarily on two key areas: (1) the Title V Senior Community Service Employment Program, which is under the direction of the Department of Labor, and (2) the remaining Older Americans Act programs which are administered by the Administration on Aging.

Senior Community Service Employment Program

First, NCBA urges the Subcommittee to approve $326 million for the Senior Community Service Employment Program (SCSEP). This is the same amount as recommended by the Administration for fiscal year 1987. Moreover, this request would match the funding level approved by Congress for FYs 1985 and 1986.

Title V has been one of the most effective programs ever developed for elderly Blacks as well as other older Americans. It is an enormously popular program which could easily be funded substantially greater than the current amount.

NCBA's Senior Employment Program typically has several applicants for each position available. Our situation is not unique because other national sponsors also have many more applicants than available positions. Consequently, we do not advertise as much as we would prefer because NCBA does not want to create false hopes for low-income older Americans who are ready, willing and able to work if given the opportunity.

NCBA is recommending a $326-million appropriation -- essentially a hold-the-line funding level -- even though the need is clearly greater, and the money would be spent well. This appropriation would restore the number of Title V positions to 63,784. Currently, the SCSEP has 63,784 positions. However, the 4.3-percent sequestration order under the Gramm-Rudman-Hollings amendment will reduce the number of Title V jobs by 2,832 on July 1, from 63,784 to 60,952.

Title V has not only been an effective program, but one that has been responsive to the needs of the minority aged. About one out of every three (34.8 percent) enrollees is a minority elderly person. Aged Blacks account for 22.8 percent of all SCSEP participants.

Over the years, Title V has consistently received strong bipartisan support from the Congress because it has been an extraordinarily successful program. The SCSEP has enabled low-income older Americans to improve their economic well-being while providing much-needed and beneficial services in their communities. The program has not been marred by fraud and abuse. Its administrative costs are low. Title V has been effective in moving older Americans into private sector employment. The unsubsidized placement rate reached 21.2 percent during the 1984-85 program year. In short, Title V has taken some of the most economically deprived older Americans in our society, and has provided them with a new lease on life.

It is a program that has worked extraordinarily well over the years -- for our nation, the older enrollees, and the communities they serve. For these reasons, we reaffirm that the SCSEP should be funded at $326 million for FY 1987, the same amount as recommended by the Administration.

Older Americans Act/Administration on Aging

NCBA further urges the Subcommittee to fund Older Americans Act programs under the direction of the Administration on Aging at their FY 1986 levels before the sequestration order became effective. This is essentially the same as the Administration's request, with one exception. The Administration is calling for a 50-percent reduction for Title IV research, training and special projects.

We strongly urge the Subcommittee to reject this measure. Title IV has already sustained hefty cuts during the early years of this Administration. A $12.5 million funding level, in our judgment, would seriously cripple this program. Title IV is necessary to complement Title III supportive and nutrition services. It is also vital to develop the cadre of trained personnel to serve older Americans now and in the future.

NCBA, therefore, recommends that funding for Title IV be frozen at the congressionally-approved appropriation levels for FYs 1985 and 1986: $25 million. We further recommend that other Older Americans Act programs be funded at their pre-sequestration FY 1986 levels: $265 million for supportive services and senior centers; $336 million for the congregate meals; $67.9 million for home-delivered meals; $7.5 million for grants to Indian tribes; and $200,000 for the Federal Council on the Aging.

An estimated $223 million metals could be served to older Americans during FY 1987 with this appropriation, including 160 million in group settings and 63 million home-delivered meals. Moreover, 9.3 million older Americans would be able to receive a wide range of supportive services, such as home health care, homemaker services, legal services, transportation, information and referral and numerous others.

NCBA also recommends that the Subcommittee approved report language to encourage state and area agencies on aging to promote minority participation in Title III supportive and nutrition services. This is necessary because the minority aged's participation rate has dropped sharply in recent years. The older minority participation rate for Title III supportive services has declined by 19.7 percent, from 21.9 percent in FY 1980 to 17.5 percent in 1984. In fact, the minority participation rate for supportive services has fallen every year since 1980 except for 1982, when it remained unchanged.

A similar pattern exists for the nutrition program for the elderly. The minority participation rate has declined by 8.9 percent, from 19.0 percent in 1980 to 17.3 percent in 1984.

A recent Civil Rights Commission report and other earlier studies have concluded that older minorities have been underserved by Administration on Aging programs, especially when measured against their greater need for services. We, therefore, urge the Subcommittee again to incorporate specific report language to help assure that aged minorities are served more equitably. This is particularly important because elderly minorities are typically two to three times as likely to be poor as aged Whites. Almost one out of every two Blacks 65 or older is either poor or marginally poor.

We also urge the Subcommittee to approve report language to promote the funding of historical Black colleges. We believe this is necessary to encourage more minorities to enter the field of aging and to focus more attention on the special services needs of older Blacks.

Conclusion

In conclusion, the National Caucus and Center on Black Aged is recommending a "hold-the-line" budget for Older Americans Act programs, although a need exists for greater funding to respond to the major problems confronting older Blacks and other older Americans. We are making these recommendations because of the tight budget situation.

Our proposals, we strongly believe, are realistic, reasonable, and substantively sound. The funding levels, with one exception, parallel the Adminstration's budget recommendations and amounts approved earlier by this Subcommittee and Congress for FY 1986. We, therefore, urge the Subcommittee to approve these measures when the FY 1987 Labor-HHS-Education Appropriations bill is considered.

STATEMENT OF MICHAEL URQUHART, PRESIDENT, AMERICAN FEDERATION OF GOVERNMENT EMPLOYEES, AFL-CIO

Senator WEICKER. Our next witness is Michael Urquhart, president of local 12, American Federation of Government Employees.

Mr. URQUHART. Thank you, Mr. Chairman.

I welcome this opportunity to testify on the Department of Labor's budget request for fiscal year 1987. I am appearing before you on behalf of the American Federation of Government Employees Local 12, which represents 5,000 employees at the Department of Labor in the Washington metropolitan area.

The proposed budget for fiscal year 1987 which provides funding at a level roughly equivalent to the two previous years is clearly not sufficient. Numerous studies, congressional hearings and reports have detailed the weaknesses in the Department of Labor's programs, including enforcement of ERISA, health and safety standards and regulations, fair labor standards acts, black lung and workers compensation programs.

The impact of 5 years of budget cuts, reducing the Labor Department's budget 50 percent and employees 25 percent can be seen in the recent statistics on occupational injuries and illnesses. After declining from 1979 through 1983, the number of work-related injuries and illnesses rose 11.7 percent in 1984, the last year for which data is available.

This represented an increase of 500,000 injuries and illnesses, 500,000 people who have suffered because the Occupational Safety and Health Administration lacks the resources to guarantee every American a safe and healthy workplace. The Labor Department has also been adversely affected by the mindless Gramm-Rudman-Hollings cuts required in fiscal year 1986. That reduction has been concentrated in personnel costs. Furloughs in some agencies are anticipated, and we expect as much as 6 days in the Employment and Standards Administration and possibly 2 days in the Mine, Safety, and Health Administration.

Training has been postponed or canceled, transfers and reassignments are widespread, and a general sense of turmoil exists that disrupts all programs. The possibility of even more substantial cuts in fiscal year 1987 has caused fear among all employees and reduced their morale and productivity.

Turning now to some of the specific program cuts, I would like to talk first about the Job Corps. Last year, the administration proposed the elimination of the Job Corps Program. The basis for their argument was rejected by both Houses of Congress. This year, they propose a 45-percent cut, and the justification remains basically the same and should be similarly rejected.

Funding at the proposed level will provide only 22,000 training slots compared to the previous 40,000. No one has argued that there is not a need for a full Job Corp Program, nor can other programs such as JTPA make up the difference. The administration proposes the elimination of the least cost-effective Job Corps centers, but they have the tools to correct that problem. If contractors did not take corrective action and if their performance remains below standard, then their contract is not renewed; and their contract can be given to someone else.

This type of forceful management can reduce the cost of the Job Corps, while continuing to provide for the full 40,000 training slots.

While the administration continues to profess a desire to get people off welfare, it once again is proposing to eliminate the Work Incentive Program, which is one of the few programs which has been successful in achieving that goal. Many of the successful State programs, such as California's Greater Avenues for Independence and Massachusetts' ET Choices, depend on the WIN Program for funding. Indeed, as the American Public Welfare Association has noted, "The WIN Program is currently the single Federal strand holding together the State's innovative welfare employment programs."

Governor Dukakis of Massachusetts has noted "It is penny-wise and pound-foolish to cut these funds. This program represents a tremendous opportunity to break the welfare cycle and help welfare recipients become taxpaying members of society."

The administration is again proposing elimination of the Mass Layoff/Plant Closing Program. Any thought that the program was no longer necessary in the current economic climate was given a rude shock when the unemployment rate surged upwards and massive layoffs hit the oil industry. In spite of the continual political and budgetary problems afflicting this program, progress was made in fiscal years 1985 and 1986.

To date, 43 States and the District of Columbia are committed to the program. Just in conclusion, let me just mention the President's Commission on Employing the Handicapped. We sympathize with the comments of the chairman. We would like to point out, though, that if the funds are transferred to another agency, that you take consideration of the needs of the employees who currently work for PCEH, some of whom who are handicapped, and that accommodation be made for them.

Senator WEICKER. I couldn't agree with you more.

Mr. URQUHART. Thank you very much.

PREPARED STATEMENT

Senator WEICKER. Thank you very much.

[The statement follows:]

STATEMENT OF MICHAEL URQUHART

I welcome this opportunity to testify on the Department of Labor's budget request for fiscal year 1987. My name is Michael Urquhart. I am appearing before your committee on behalf of the American Federation of Government Employees, Local 12, which represents 5,000 Department of Labor employees in the Washington metropolitan area.

The Department of Labor was established to promote the welfare and working conditions of working people in this country. Clearly, it cannot fulfill that mission if it is denied the resources to carry out the programs that have been developed over the years and mandated by Congress. The proposed budget for FY 87, which provides funding at a level roughly equivalent to the two previous years, is clearly not sufficient. Numerous studies, Congressional hearings, and reports have detailed the weaknesses in the Department of Labor's programs, including enforcement of ERISA, health and safety standards and regulations, Fair Labor Standards Act, and Black Lung and Workers Compensation programs.

We understand the budget problems facing Congress this year. But we cannot, in good conscience, sit idly by while Department of Labor programs are inadequately funded, and when the lack of enforcement increases the danger to the health and safety of every American. If the job is worth doing, we have always been told, it is worth doing well.

The impact of 5 years of budget cuts, reducing the Labor Department's budget 50 percent and employees 25 percent, can be seen in the recent statistics on occupational injuries and illnesses. After declining from 1979 through 1983, the number of work-related injuries and illnesses rose 11.7 percent in 1984, the last year for which data is available today.

This represented an increase of half a million injuries and illnesses, half a million people who have suffered because OSHA lacks the resources to guarantee every American a safe and healthy workplace.

The Labor Department has also been adversely affected by the mindless Gramm-Rudman-Hollings (G-R-H) cuts required in FY86. The 4.3 percent reduction has been concentrated in personnel costs. Furloughs in some agencies are anticipated. Training has been postponed or cancelled. Transfers and reassignments are widespread. And a general sense of turmoil exists that disrupts all programs. The possibility of even more substantial G-R-H cuts in FY87 has caused fear among all employees, and reduced their morale and productivity.

The continual budget upheaval, where programs are proposed for elimination, and then later given funding, or where cuts are made in mid-fiscal year, only to be restored in the next fiscal year, makes effective management of these programs extremely difficult and long range planning impossible.

I would like to turn now to some of the specific proposals in the Department's budget request for FY 87.

1. REDUCTION OF THE JOB CORPS.

Last year the Administration proposed the eliminantion of the Job Corps program. They argued that the program was expensive and inefficient, and that its goals could be achieved through the Job Training Partnership Act (JTPA). This argument was rejected by both houses of Congress.

This year they propose a 45% cut from the FY86 level. The justification for this cut remains the same, and should be similarly rejected.

Funding at the proposed level will provide only 22,000 training slots, compared to the previous 40,500. No one has argued that there is not a need for a full Job Corps program. Nor can other programs, such as JTPA, make up the difference. JTPA was never designed to reach the population that the Job Corps does -- disadvantaged youths with little prospect of employment.

The administration is proposing the elimination of the least cost effective Job Corps centers. This only makes the disadvantaged youths suffer for management mistakes. The Department of Labor has the tools to take action against ineffective and poor management of the centers. If contractors do not take corrective action, and if their performance remains below standard, then their contract is not renewed and the contract can be given to someone else.

This type of forceful management can reduce the cost of the Job Corps, while continuing to provide for 40,000 training slots.

The Department of Labor also does not consider the cost of closing the centers. Thirty of the centers are part of the Civilian Conservation Corps, and are staffed by Federal employees. Any shutdown would result in Reductions in Force with all the disruption and added costs that we have learned are associated with such actions.

In the final analysis, reduction or eliminantion of the Job Corps simply does not make fiscal sense. In spite of all the Administrations attempts at justifications for its actions, no one has challenged the results of the Mathematica Study which showed that the Job Corps returns $1.46 for every $1.00 spent.

Previously, the Labor Department had characterized the program as "the last, best hope to join the societal mainstream" for the youth that it serves. With youth unemployment at about 18 percent, and the jobless rate for black youth over 40 percent, the Job Corps is a beacon of hope. Don't take away that hope.

2. WORK INCENTIVE PROGRAM (WIN)

While the Administration continues to profess a desire to get people off welfare, it is once again proposing to eliminate the Work Incentive Program (WIN), which is one of the few programs which has been successful in achieving that goal. Unfortunately, the Senate budget committee has also endorsed this proposal.

WIN has proven itself as a cost effective program that has demonstrated its ability to assist AFDC recipients and applicants to find unsubsidized employment. Approximately 75% of those served are single mothers who would not be assisted by JTPA. The $165 million budget of the WIN program is less than half of what the program saved last year in lower AFDC payments.

Many of the successful state programs, such as California's Greater Avenues for Independence (GAIN) and Massachusetts' ET Choices depend on the WIN program for funding. Indeed, as the American Public Welfare Association has noted the "WIN program [is] currently the single federal strand holding together the states' innovative welfare employment programs."

The Massachusetts program has resulted in a cut in the welfare caseload from 93,000 to 84,000 families, at a saving to the state and federal governments of about $70 million.

As Governor Dukakis has noted, "It's penny-wise and pound-foolish to cut these funds. This program represents a tremendous opportunity to break the welfare cycle and help welfare recipients become tax-paying members of society." (Boston Globe 2/5/85)

3. ELIMINATION OF THE MASS LAYOFF/PLANT CLOSING PROGRAM

The Administration is again proposing elimination of the Mass Layoff-Plant Closing program. Any thoughts that this program was no longer necessary in the current economic climate was given a rude shock when the unemployment rate surged upwards, and massive layoffs hit the oil industry.

Inspite of the continual political and budgetary problems afflicting this program, progress was made in fiscal years 1985 and 1986. In addition to the 8 states in ongoing production status, 32 new states and the District of Columbia finalized cooperative agreements with BLS in FY85, and 3 more states were added in FY86. To date, 43 states and the District of Columbia are committed to the program.

The mass layoff-plant closing program will provide the first truly comprehensive statistics on plant closings and their impact on laid off workers. Information generated would include the number of firms, the number of effected workers and the number of workers staying on Unemployment Insurance (UI) by state, industry and by reasons for layoff. Furthermore, a statistical sample of those who received final UI payments would be tracked for subsequent employment experience.

For the first time, the United States would have the information necessary to quantify the complex problem of plant closings and the resulting unemployment and underemployment. The statistical information generated could be important in understanding the need for UI, trade adjustment assistance, plant closing legislation and training programs like Job Corps and JTPA.

This program has generated broad support. State and local governments, private research organizations, business and labor organizations are all very interested in the plant closing and dislocated worker information. There is currently no other source for information of this type at this level of industry/area detail.

4. CONTINUATION OF THE PATC SURVEY

Local 12 urges contined funding for Professional, Administrative, Technical and Clerical Pay (PATC) survey. Although an expansion of PATC is called for in the President's budget, we understand that there has been some consideration of cuts to this program.

We believe that PATC is an important program. The PATC survey is the basis for pay comparisons under the Federal Pay Comparability Act of 1970 and is the best means available of judging where Federal employee pay is in relation to other sectors. It is also the only data available on such important occupational groups as accountants, attorneys, chemists, engineers, computer programers, system analysts, clerical workers and other occupations which are playing an increasing role in the economy. In addition, PATC is used by government agencies to estimate labor costs for proposed contracts.

SUMMARY

Federal employees understand that action must be taken to reduce the Federal budget deficit. We know this means that tough decisions must be made. But we cannot endorse budget actions which threaten the health and welfare of America's working people, and which make it difficult if not impossible for the Department of Labor to accomplish its mission and function.

Nor does it make sense to eliminate programs in the name of fiscal responsibility that have proven themselves to be cost effective, and actually save the government money at the Federal, State, and local level.

I, therefore, urge this committee to reject the Administration's proposals to eliminate the WIN and Mass Layoff/Plant Closing programs, to reduce the Job Corps, and to freeze funding for other Department of Labor programs at inadequate levels.

STATEMENT OF COL. WILLIAM P. McCAHILL, CHAIRMAN EMERITUS, PEOPLE TO PEOPLE COMMITTEE FOR THE HANDICAPPED

Senator WEICKER. The next witness is Col. William P. McCahill, chairman emeritus, People to People Committee for the Handicapped.

Mr. McCAHILL. Good morning, sir.

Senator WEICKER. Colonel McCahill?

Mr. McCAHILL. From 1937 to 1943, I was executive secretary of the President's Committee on Employment of the Handicapped. I don't presume to speak for all disabled persons, but, as a 100-percent service-connected retired Marine Reserve colonel, I have devoted and still devote a great deal of time to handicapped matters, as you know, because you and I have been together on many occasions, in church, scouting, veterans, and other efforts.

In 4 minutes, I can't present the demise of a distinguished volunteer committee which has served the Nation and the Presidency for almost 40 years. But I do have valuable institutional memories, and I appreciate your courtesy in letting me speak my piece. From its early inception in 1947 as the President's Committee on National Employ the Physically Handicapped to the shorter form, the Physically Handicapped, during the Kennedy era, adopted the words physically, the President's committee has changed.

It has stayed close to American needs as a moving and pioneering force in many projects benefiting Americans, not only in the old days in my watch, but even today. It had and still has an extremely large volunteer constituency. The last two witnesses proved that. Bill could have said the same thing when he spoke for the security employment agencies. The Committee on Volunteer Groups has made history, to mention a few you may be familiar with, helping to make buildings and environments more accessible; early efforts with the American Transport Association, and later with the Civil Aeronautics Board and the Federal Aviation Administration to improve air travel accessibility, still working on it; many programs with labor and business for gainful employment; millions of dollars of free media support; many programs of labor and business for gainful employment; a series of national awards, including a President's trophy, recognizing both individuals and groups and significantly, helping to establish and work with Governors' committees in every State in the Union, including your own.

The committee, certainly on my watch and in my retirement years as a member of working subcommittees, has brought together group after group to serve emerging needs. You said times have changed, and the committee has changed with them, sir. From the original structure of business, labor, media, educational, medical, and veterans volunteer groups, the committee involved the heads of the major national women's organizations, the cream of the Nation's designers to help design products for sheltered workshops to produce, to work on leisure and recreation, because we know that you have to have life beyond just existing, and also you mentioned living and transportation, other things.

The committee has been in the forefront and still is, in some of these areas. Today's metro possibly would not have elevators without the committee's efforts. I know that personally, because I was involved. I would have caught hell if the people it the White House had found out about it. All of this is history. But history does point to the future.

Therefore, I am puzzled at your personal decision to deny future committee funds, particularly since you have been the friend of the handicapped, the one friend of the handicapped since Jennings Randolph left.

You follow a distinguished group of predecessors. By transferring its appropriation to the national council, if this is done—and I am speaking personally, nobody sent me, I am not a messenger—if this is done, two things, to me appear obvious. The Nation and the disability community will lose an apolitical entity—we are not political, never have been—which serves to bring together many disparate groups, labor and industry, medicine and education, which are frequently fighting on the outside and always came together at our committee structures.

Its apolitical status makes willing cooperation possible, and its loss, possibly, will mean the end of significant contributions of volunteers in programs involving issues beyond employment. As an experienced bureaucrat, and I am almost through, I feel mixing an oversight role with program authority is not good administration and is doomed to failure. Nothing garners private support like the word "President."

The late Mary Switzer, whom I am sure you know or at least know of, used to say if there wasn't a President's committee we would have to invent one. A role exists for the President's committee and a national council. I hope together they will make a formidable team. I hope you won't sacrifice one for the other. If you do that, I hope we never recapture the ground we have gained over the last 40 years.

In conclusion, thank you, and may the Lord reward you and your family for the caring and sharing of the handicapped.

Senator WEICKER. First of all, thank you for coming and taking the time to testify, Colonel McCahill. It is appreciated, and your input is valuable input. Point No. 2, you have every right to be enormously proud of the work of the Presidential Committee on the Employment of the Handicapped. They, indeed, were the only, the only entity to carry the ball for the handicapped in a variety of various areas that you have spoken of.

The only point to be made, the only point that I am going to make here is were I a member of that committee, I would feel very good that finally, after all these many years of Executive order and volunteer efforts, finally, there was something in the law to guarantee the rights of the handicapped.

That is the only change that has taken place. Unfortunately, in a time of budget constraints, what we want to no is to give the greatest emphasis to those areas, to have the capacity to carry out the mission given.

I repeat, there are two separate subjects here: What has been done up to this point by the Presidential committee and the employment of the handicapped and what the future is to be. If there were no National Council on the Handicapped, I would, however, never advocate the abolition of PCEH, never.

I think we are far better off, however, with the council as being a creature of law. Nobody except the Congress of the United States can eliminate that activity for the emphasis that that group now gives to the needs of the handicapped.

So I just want you to feel, No. 1, very much appreciated as an individual for taking the time to be here; for the efforts that you have made over the years, and for the efforts of the council itself. Let me say this, too: That like everything else in this town, you know, it probably will be a long time before it goes. Once you start something, you can't very well finish it. It is not that easy.

But in terms of concept, you and I are exactly on the same side of the street, fighting the same fight with the same amount of energy. There is no difference on that count whatsoever.

Mr. McCahill. Could I make one comment?

Senator Weicker. Sure.

Mr. McCahill. It is hardly my point to correct a member of the U.S. Senate, and I have been warned not to do this. In fact, they told me you would eat me alive. [Laughter.]

Senator Weicker. I can't imagine that anybody would say that about me. [Laughter.]

Mr. McCahill. Well, sir, you keep saying, your staff keeps saying that the President's Committee is only an Executive order. It is titled in code, the joint resolution of the Congress signed by the President of July 11, 1949. It is in the same code that your national council is in, Senator. I don't know why your staff doesn't tell you that.

Senator Weicker. All right. If I am in error on that point, I accept the correction.

Mr. McCahill. That is wonderful.

Senator Weicker. I bow gracefully. It does not, however, it does not obviate the new role now being played by the National Council on the Handicapped.

Mr. McCahill. I didn't come here to change your mind, Senator. I know you have made up your mind. I do want to make that correction, and also, can you legislate in the appropriation act? Because I think that is what you are going to be doing.

Senator Weicker. Of course, this paper that you gave me is an Executive order.

Mr. McCahill. But in the first paragraph there, it refers to the joint resolution of the Congress in 1949.

Senator Weicker. I will certainly take a look at this aspect of it.

Mr. McCahill. Thank you, sir.

Senator Weicker. Thank you very much.

Mr. McCahill. I hope we will meet on a happier occasion. God bless you.

Senator Weicker. Let me put it this way. I think you keep slugging away the why you are doing, and the handicapped are the better off for it. I enjoy a fighter, believe me.

Mr. McCahill. I spent 40 years in the Marine Corps, sir, and we weren't exactly pacifists. [Laughter.]

PREPARED STATEMENTS

Senator Weicker. You are always welcome before this committee, too. Your statement will be included in the record at this point along with other statements for the record on appropriations for the Department of Labor.

Mr. McCahill. Thank you, sir.

[The statements follow:]

Statement of Col. William P. McCahill

My name is William P. McCahill. From 1947 to 1973, I served as executive secretary of the President's Committee on Employment of the Handicapped. I do not presume to speak for all disabled persons. But, as a 100-percent service-connected retired Marine Reserve colonel, I have devoted and still devote in retirement considerable volunteer efforts in church, scouting, veterans, and other efforts for handicapped.

In 4 minutes, I cannot hope to prevent the demise of a distinguished volunteer committee which has served the Nation and the Presidency for 40 years. I believe that I have valuable institutional memories and appreciate the chairman's invitation to share my views.

From early inception as the President's Committee on National Employ the Physically Handicapped Week, through the transition to its short form, on Employment of the Physically Handicapped, to its present form so as to include retarded and emotionally handicapped persons, the committee has stayed close to American needs as a moving, pioneering force in many projects today's disabled persons take for granted. It has had and still has an extremely large volunteer constituency.

The committee, together with its volunteer groups has made history, to mention only a few: making buildings and environments more accessible; early efforts with the Air Transport Association and later with the Civil Aeronautics Board and Federal Aviation Administration to improve air travel accessibility; many programs of labor and business for gainful employment; millions of dollars of free media support; a series of national awards, including the President's trophy to recognize both individuals and groups, and significantly helping to establish Governor's committees and local committees.

The committee, certainly on my watch and in my retirement years as a member of various working PCEH committees, brought together group after group to serve emerging needs. From the original structure of business, labor, media, educational, medical, and veterans volunteer working cadres, the committee involved the heads of the major national women's organizations, the cream of the Nation's designers to develop products for sale by sheltered workshops and leaders in recreation and leisure and youth groups working on specific beneficial programs. The committee well knows that gainful employment also requires available transportation to work and living accommodations. Today's metro here possibly would not have elevators without the committee's efforts.

All of this is history, but history does point to the future, and, therefore, I am puzzled at this subcommittee's desire to deny future PCEH funding by transferring its appropriations to the national council. If this is done, two things appear to me to be obvious: (1) the Nation and the disability community will lose an apolitical entity with a proven ability to bring together disparate groups to serve disabled persons. Its apolitical status makes willing cooperation possible and its loss probably will also mean the end of significant contributions of volunteers in programs involving issues beyond employment; (2) as an experienced bureaucrat, I feel mixing an oversight role with program authority is not good administration and is doomed to failure. Nothing garners private support like the word "President" which symbolizes national commitment. The late Mary Switzer frequently said that "if there wasn't a PCEH we'd have to invent one." A role exists for both a PCEH and a national council, together a formidable team. Let's make better, not sacrifice one for the other. If you sacrifice PCEH we may never recapture the high ground won these past 40 years. Thank you and may the Lord reward you for your past caring, sharing.

Presidential Documents

Executive Order 11480

THE PRESIDENT'S COMMITTEE ON EMPLOYMENT OF THE HANDICAPPED

By virtue of the authority vested in me as President of the United States, and in order to provide for the carrying out of the provisions of the Joint Resolution approved July 11, 1949, ch. 302, 63 Stat. 409, as amended, and the provisions of section 8 of the Vocational Rehabilitation Act, as amended (29 U.S.C. 38), it is ordered as follows:

SECTION 1. *Establishment and composition of the President's Committee.* (a) There is hereby established the President's Committee on Employment of the Handicapped (hereinafter referred to as the Committee or as the President's Committee).

(b) The Committee shall be composed of a Chairman and not more than four Vice Chairmen, who shall be appointed by and serve at the pleasure of the President, and of so many other members as may be appointed thereto from time to time by the Chairman of the President's Committee from among persons (including representatives of organizations) who can contribute to the achievement of the objectives of the Committee. Members appointed by the Chairman shall be appointed for a term of three years and may be reappointed. The Chairman of the President's Committee may at any time terminate the service of any member of the President's Committee, except any member appointed by the President.

(c) The Chairman of the President's Committee, upon the advice of the Executive Committee (hereinafter provided for), may designate as, or invite to be, associate members of the President's Committee any heads of Federal departments and agencies which have responsibility for rehabilitation services or promotional activities touching the field of interest of the Committee or which are leading employers of handicapped personnel.

(d) Representatives of industry, labor, public and private agencies, and other concerned organizations and individuals may be invited to attend meetings of the Committee.

SEC. 2. *Functions of the Committee.* The President's Committee shall facilitate the development of maximum employment opportunities for the physically handicapped, mentally retarded, and mentally restored. To this end the Committee shall supply information to employers, labor unions, and national and international organizations, conduct a program of public education, promote cooperation between organizations and agencies, and enlist the support of Federal officials, State and local officials, Governors' and local Committees on Employment of the Handicapped, professional organizations, organized labor, and appropriate international organizations. In carrying out the functions vested in it by section 8 of the Vocational Rehabilitation Act, as amended, the Committee shall work closely with the Department of Labor, Department of Health, Education, and Welfare, the Veterans Administration, State employment-security agencies, and State vocational rehabilitation agencies.

SEC. 3. *Executive Committee.* (a) There is hereby established the Executive Committee of the President's Committee on Employment of the Handicapped. The Executive Committee shall be composed of the Chairman of the President's Committee, who shall also be the Chairman of the Executive Committee, the Vice Chairmen of the President's Committee, and so many additional members as will provide an Executive Committee of not less than fifteen and not more than fifty members. The said additional members shall be appointed annually by the Chairman of the President's Committee, from among the members of the President's Committee or otherwise. The Chairman of the President's Committee may at any time terminate the service of any member of the Executive Committee.

(b) The Executive Committee shall advise and assist the Chairman of the President's Committee in the conduct of the business of the President's Committee and, as authorized by the President's Committee or the Chairman thereof (with due regard for the responsibilities of other Federal agencies), shall study the problems of the handicapped in obtaining and retaining suitable employment, invite authorities in the various professional, technical, and other pertinent fields to assist in the exploration of those problems, and review and develop plans and projects for promoting the employment of the handicapped.

SEC. 4. *Advisory Council.* There is hereby established the Advisory Council on Employment of the Handicapped, which shall advise the President's Committee with respect to the responsibilities of the Committee. The Council shall be composed of the Chairman of the President's Committee, who shall also be the Chairman of the Council, and of the following-named officers, or their respective alternatives: The Secretary of Agriculture, the Secretary of Commerce, the Secretary of Labor, the Secretary of Health, Education, and Welfare, the Secretary of Housing and Urban Development, the Secretary of Transportation, the Administrator of Veterans' Affairs, and the Chairman of the United States Civil Service Commission.

SEC. 5. *Administrative and incidental matters.* (a) The President's Committee, the Executive Committee, and the Advisory Council shall each meet on call of the Chairman of the President's Committee at a time and place designated by him. In the case of the President's Committee and the Executive Committee, the Chairman shall call at least one meeting and two meetings, respectively, to be held during each calendar year.

(b) In the absence of designation by the President, the Chairman of the President's Committee may from time to time designate a Vice Chairman of the President's Committee to be one or more of the following-named in the absence of the Chairman: Acting Chairman of the President's Committee, Acting Chairman of the Executive Committee, and Acting Chairman of the Advisory Council. The Chairman of the President's Committee shall from time to time assign other duties to the Vice Chairman thereof.

(c) The Chairman of the President's Committee shall on behalf of the President direct the President's Committee and its functions.

(d) The Chairman may from time to time prescribe such necessary rules, procedures, and policies relating to the President's Committee, the Executive Committee, and the Advisory Council, and their affairs, as are not inconsistent with law or with the provisions of this order.

(e) The Vice Chairmen shall advise and counsel the Committee and shall represent the Committee on appropriate occasions.

(f) All members (including the Chairman and Vice Chairmen) of the President's Committee, the Executive Committee, and the Advisory Council shall serve without compensation. The Chairman and the Vice Chairmen of the President's Committee may receive transportation and per diem allowances as authorized by law for persons serving without compensation.

(g) Employees of the President's Committee shall be appointed, subject to law, and shall be directed, by the Chairman of the Committee. To such extent as may be mutually arranged by the Chairman of the Committee and the Secretary of Labor, employees of the Committee shall be subject to the administrative rules, regulations, and procedures of the Department of Labor.

(h) The Department of Labor is requested to make available to the President's Committee necessary office space and to furnish the Committee, under such arrangements respecting financing as may be appropriate, necessary equipment, supplies, and services. The estimates of appropriations for the operations of the Committee shall be included within the framework of the appropriation structure of the Department of Labor, in such manner as the Director of the Bureau of the Budget may prescribe. The Chairman of the Committee, in cooperation with the Assistant Secretary for Administration of the Department of Labor, shall be responsible for the preparation and justification of the estimates of appropriations for the Committee.

SEC. 6. *Prior orders; transition.* (a) To the extent that this order is inconsistent with any provision of any prior order, or with any provision of any regulation or other measure or disposition, heretofore issued, made, or taken by the President or by any other officer of the executive branch of the Government, this order shall control. Executive Order No. 10994 of February 14, 1962, and Executive Order No. 11018 of April 27, 1962, are hereby superseded.

(b) Without further action by the President or the Chairman of the Committee, all members, employees, records, property, funds, and pending business of the President's Committee on Employment of the Handicapped provided for in Executive Order No. 10994 of February 14, 1962, as amended, shall on the date of this order become members, employees, records, property, funds and pending business of the Committee established by this order.

(c) The tenure of persons as members of the Committee in pursuance of the provisions of section 6(b) of this order, (i), in the case of persons appointed to the predecessor Committee by the President, shall be at the pleasure of the President, and (ii), in the case of other members, shall be for periods equal to their respective unexpired terms under Executive Order No. 10994, as amended, but shall also be subject to the provisions of the last sentence of section 1(b) of this order.

Richard Nixon

THE WHITE HOUSE,
September 9, 1969.

STATEMENT OF LILLIAN ROBERTS, COMMISSIONER, NEW YORK STATE DEPARTMENT OF LABOR

Mr. Chairman, members of the Subcommittee, I am Lillian Roberts, Commissioner of the New York State Department of Labor. I appreciate this opportunity to present the views of the state of New York concerning FY 1987 appropriations for the programs under my jurisdiction.

While many of Federally funded programs we administer will be coming before you for action I would like to concentrate my remarks on three. They are the Work Incentive Program, the Targeted Jobs Tax Credit, and the Summer Youth Employment Program under the Job Training Partnership Act.

Work Incentive Program (WIN)

Over the past five years the WIN program has constantly been threatened with extinction. Each year Congress has acted to keep it operating, albeit at a reduced level. Nationally, the program has been reduced by $100 million in this five year period or about one-third. We believe strongly that the decision to continue the program was and is a wise one. WIN continues to be a major force in helping welfare recipients break the cycle of poverty through employment. As you may be aware, New York State has an extensive program of job placement related programs for its welfare recipients and Governor Cuomo's new work-not-welfare initiatives will increase our State investment in this process even more. However, the overall strategy on which these State programs are based includes as a key element, the availability of a viable WIN program. An additional component in that strategy is maximum use of JTPA resources for welfare recipients. However, we must face the reality that JTPA cannot be all things to all people and even though the Governor has exercised his option to adjust JTPA Performance Incentives to stress services to welfare recipients, many other eligible client groups must be addressed as well. To expect JTPA to fill the gap in service to AFDC recipients is simply and totally unrealistic.

New York's work-not-welfare program is proposed, not because WIN is ineffective - in Fiscal Year 1986 we expect that over 20,000 WIN registrants will secure employment. That represents a cost per participant entered employment of approximately $850. The potential savings are obvious. Rather, our new welfare initiatives are proposed because neither WIN alone nor WIN and JTPA working together are enough to meet the needs. New York projects 60,000 new public assistance recipients during FY'87. These are among the most likely to benefit from WIN services. Any reduction in WIN appropriations will substantially impact on our ability to serve these and the other employable recipients who need the services only WIN can provide.

Targeted Jobs Tax Credit (TJTC)

The Targeted Jobs Tax Credit Program has a major impact in the State of New York. New York has led the nation in implementing this program. TJTC is responsible for the hiring of 51,210 disadvantaged individuals. Included in this total were 13,174 welfare recipients. Not only does TJTC serve to restore some equity to economically and sociologically disadvantaged job seekers it also combines with other programs to make them more effective. It is a key element in their job development structure. In New York City for example, the successful Summer Youth Employment Program operated under the aegis of the New York City Partnership, Inc. with the full participation of the State Department of Labor, makes heavy use of TJTC to generate private sector summer jobs. Many other programs have found it to be a critical element of their job placement programs and a strong encouragement to retention of the new worker through early periods of acclimitization.

The inclusion of a retroactive TJTC renewal in both the Senate and House tax packages is affirmation of Congress' recognition of the value of this program. What the States will need, and in particular those of us who optimistically kept our TJTC staffs on board through the hiatus period, is a full annual appropriation in order to process all of the certification requests since January 1, 1986. Your acknowledgment of the significance of TJTC must, in other words, extend to providing us with the resources to operate effectively.

Summer Youth Employment Programs (JTPA Title IIB)

Summer Youth Employment Programs have been targeted for significant reductions as overall unemployment decreased. This action disregards the current unacceptable level of youth unemployment and the intense competition for jobs that provide full time employment for younger workers.

We believe the problems caused by these reductions would be compounded rather than reduced by the USDOL proposal to target these funds only to areas with the greatest number of unemployed youth. Despite the projection that New York State locations would probably get a higher allocation level overall from targeting approach we are not in favor of it.

Among New York's 34 service delivery areas some of the smallest are the least able to provide resources to cope with their problems. The complete elimination of these Service Delivery Areas because their need is comparatively small prohibits them from leveraging funds to provide jobs and other vital services for their young job seekers. In New York, IIB funds have been combined with State appropriations not only to find summer employment but to provide related educational and vocational exploration services that clarify a youth's vocational plan and bring an appreciation of the role of education in achieving employment objectives.

Such programs have both immediate and long-term benefits vital to the economy of all of our State's Service Delivery Areas, not just those with the highest level of need.

New York State's growing economy provides real opportunity for employment and training programs to achieve notable successes on behalf of its clients. People long inhibited from full and productive participation in the work force can now be helped to achieve self-sufficiency and independence. The programs we've discussed are a significant part of that process and part of an overall thrust to provide the work force needs of the future. The nation's investment in its human resources should not be reduced when human resources are so critical to our economic health and prosperity and when the returns on that investment are steadily increasing.

LETTER FROM KENNETH R. TOBIN, VICE PRESIDENT OF GOVERNMENT RELATIONS AND NATIONAL AFFAIRS, NATIONAL SAND & GRAVEL ASSOCIATION

March 31, 1986

The Honorable Lowell P. Weicker, Jr.
United States Senate
Washington, DC 20510

Dear Senator Weicker:

The National Sand and Gravel Association wishes to reiterate its strong support for continuing a provision in the 1987 Labor-HHS-Education Appropriations bill that prohibits the Mine Safety and Health Administration from enforcing its training regulations against the sand and gravel industry. This provision has been in effect since fiscal year 1980. During the past seven years, the safety record of this industry has steadily improved due in no small part to the regulatory relief provided by this provision.

For the first nine months of 1985 (the latest period for which data is available), the all-incidence rate (fatalities and injuries) for the sand and gravel industry was 3.21. This favorably contrasts with a 5.79 rate for metal mines, a 3.95 rate for other nonmetal mines and a 6.44 rate for coal mines.

Last year, the Mine Safety and Health Administration irresponsibly consolidated all safety and health regulations for the metal and nonmetal mining industries, eliminating separate standards for the sand and gravel operators. MSHA has also proposed issuance of revised training regulations which consolidate all federal mine training requirements into a single regulation. We strongly oppose this consolidation, not only for training regulations, but for all regulations, since it serves to blur the distinctions between the various types of mining and creates the kinds of problems which required Congressional action in the first place. It underscores our contention that sand and gravel producers will be lumped together with other dissimilar types of mining, instead of being subject to separate standards appropriate to our types of operations.

We urgently request that you support continuation of the training regulation exemption for fiscal year 1987. Enclosed is an updated version of a statement this Association has previously filed with the Appropriations Committee which outlines our position on this matter. We will be happy to provide any additional information you might require on this subject.

Sincerely yours,

Kenneth R. Tobin

Kenneth R. Tobin
Vice President of Government
Relations and National Affairs

STATEMENT OF KENNETH R. TOBIN

The National Sand and Gravel Association strongly supports retention of the provision in the 1980, '81, '82, '83, '84, '85 and 1986 Labor Department Appropriations bill denying the Mine Safety and Health Administration funds to enforce its impractical training regulations against the sand and gravel industry. We ask that the Congress again renew this prohibition for fiscal year 1987 until permanent legislative relief has been granted to our industry.

The member companies of the National Sand and Gravel Association, and indeed most of the companies in our industry, maintain strong and effective safety programs as our ever-improving safety record demonstrates. We believe that, both from a moral and practical business standpoint, good safety programs make good sense. However, the kind of flexibility needed by small operations, which comprise the bulk of our member companies, is not provided by MSHA's current training regulations and, unfortunately, is impossible to obtain under the existing law.

Under the previous Act (Federal Metal and Nonmetallic Mine Safety Act), we endorsed and supported specific regulations which required training to meet the standards. We have developed and made available to the industry training programs and materials and have recommended training aids developed by other organizations.

The sand and gravel industry is deeply grateful to the Congress for the action taken in our behalf through the appropriations process of denying MSHA funds to enforce these burdensome standards. We have encouraged our members to continue training their employees in safe work practices, and all indications are that they are continuing to do so.

One major area of confusion, with respect to MSHA's training regulations, is the fact that there are actually five separate types of training required, three of which must be given by MSHA licensed instructors. The five separate types of training are:

Types	Length	MSHA Approved Instructor Required
1. New Miner	24 Hours for Surface	Yes
2. Newly Employed Experienced Miner	Set by Operator - Subject to MSHA Approval	Yes
3. Annual Refresher	8 Hours	Yes
4. Task	Set by Operator - Subject to MSHA Approval	No
5. Hazard	Set by Operator - Subject to MSHA Approval	No

We do not know of a single sand or gravel producer who has any intention of jeopardizing the safety and health of his employees because an employee does not know how to do his or her job in a safe manner. The type and amount of training varies from one location to another and even from one type of job to another within individual operations. The final regulations, from which we seek relief, require that we provide a number of training courses which are unnecessary. For example, there is no reason to provide training with respect to highwalls, mine illumination, or mining methods, to each and every employee who goes to work for us. There is a serious question as to whether each and every employee in the sand and gravel industry should be certified in first aid before beginning any work.

Certainly an appropriate number on each shift should be first-aid qualified as is required by an existing mandatory standard (30 CFR, Chapter 1 - Subchapter N, Part 56.18-10), but to require eight or ten hours of training for each person hired in the industry goes beyond the realm of reason.

All of these requirements, including MSHA approved instructors, are mandated on an industry with an average of less than seven employees per operation and with employee turnover rate exceeding 40 percent annually. We intend to train our employees in the safe manner in which to perform their assigned job, but cannot, and wholeheartedly believe it unnecessary, to comply with the bureaucratic burdens of MSHA's training regulations.

The problems experienced by the members of our Association with the 1977 Federal Mine Safety and Health Act are not limited to the training requirements of the Act. We will continue to press for permanent legislative relief. Until such time as that relief is obtained, the training prohibition provision, first provided by the Congress in 1979, is absolutely essential to the economic well-being of our industry. We will continue to strive for a safe work environment for our employees as we have done these past five years that the training restrictions have been in effect. We need, however, to be free of the heavy-handed requirements of MSHA to be able to guarantee continuing improvement in the safety record of our industry.

STATEMENT OF WOODROW A. MYERS, JR., M.D., INDIANA COMMISSIONER OF HEALTH, ON BEHALF OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Senator WEICKER. As we now move to the Centers for Disease Control, the next witness is Woodrow Meyers, the Association of State and Territorial Health Officials. He is the Indiana commissioner of health.

Dr. MYERS. Thank you, Senator.

Senator WEICKER. Dr. Myers?

Dr. MYERS. I am a physician and the State health commissioner for the State of Indiana. I am speaking to you today as a representative of the Association of State and Territorial Health Officials. The Centers for Disease Control is an outstanding organization dedicated to developing and applying the technology and methodology needed to prevent unnecessary illness and premature death.

This task is accomplished through an extremely close relationship between the CDC and the State health departments at the present time. We work synergistically to ensure that the scientific breakthroughs of the National Institutes of Health and the major medical centers around the world are effectively applied for the benefit of the American people. The importance of this task in the scheme of Government is clearly a criticality one. Our prior accomplishments and the prospects for improvement in the Nation's health are threatened by the funding cuts proposed in the fiscal year 1987 CDC budget.

All of us understand the importance of balancing the Federal budget, but the mission of the CDC should not be placed at risk in order to achieve budget targets that, with respect to health, are illogical.

The Association of State and Territorial Health Officers asks you to correct these errors and asks that the mission be allowed to continue.

The preventive health services block grant is clearly the backbone of public health. It is the only source of Federal funds specified for prevention activities available to the States. Programs targeted by the preventive health block grant include hypertension reduction, health education, dental health, emergency medical services, and violence prevention.

In the fall of 1985, then Secretary Margaret Heckler released her task force on black and minority health. She found that on average, 59,000 black American men, women, and children die each year in excess of the predicted mortality if those black men, women, and children had the same mortality rates of that in the white American population. That means that today, April 24, 161 black Americans will die unnecessarily because of factors either directly or indirectly attributable to race.

The task force made a series of recommendations to eliminate this disparity, but no new Federal funds were provided to the States to meet this challenge. In the State of Indiana, we have relied on our preventive health block grant to meet these needs. Such efforts are beginning in many other States but are sure to be aborted should the proposed cuts take place.

It is especially troublesome that the administration has chosen to either reduce or straight-line components of the CDC immunization budget. Nowhere are the data supporting prevention activities more clear cut. Vaccination substantially decreases disease and reduces net medical costs. Your own Office of Technology Assessment concluded that a 1983 comprehensive program using a combined vaccine for measles, mumps, and rubella would have saved $387 million in direct treatmemt costs and paid for the vaccination program. These cost savings would have also saved 800 lives and prevented 4,000 cases of encephalitis, which is a complication of this disease. It is shortsighted, and it is wrong to underfund immunization when the data are so clear that investment in immunization programs significantly benefit our children and their parents. If caught in time, tuberculosis is a disease that can be treated. If not caught in time, tuberculosis will kill.

The American Lung Association documents a 2-percent increase in the number of tuberculosis cases identified in the United States last year. Yet, there are no funds provided in the CDC budget for tuberculosis control. It has been eliminated. A study done in Connecticut for the Connecticut State Health Department saved $81,000 last year in hospitalization costs from the money invested in tuberculosis control clearly shows the cost-benefit equation with respect to tuberculosis funding.

The final category of expenditures I wish to address is that for the acquired immune deficiency syndrome [AIDS]. Although Congress has been generous with respeat to its appropriation for AIDS, the fiscal year 1987 request is not sufficient to meet the need to control the Nation's No. 1 public health problem. Although it is quite appropriate to invest in the search for effective treatments and for a vaccine, the only weapon currently available is that of education for prevention.

Virtually all of that effort stems from programs at the State and local level. It is crucial that Congress restore funding for alternative test sites and that the Congress substantially increase funding for health, education, and risk reduction. In San Francisco and in New York, approximately 75 percent of the high-risk population has already been infected by the virus. For them, medical science and public health have little to offer, for once infection occurs, the virus replicates and spreads to others through sexual contact.

In Indiana, only 20 percent of our high-risk population has been exposed to the virus, and we have an opportunity to keep from becoming a San Francisco or a New York, as do many other States.

In conclusion, there is no longer a question about the value of prevention. It costs us $800 in Indiana to care for an expectant mother prior to delivery. We know that mothers who do not receive such care are three times as likely to deliver low birth weight infants requiring hospitalization.

In Indiana, it costs society $18,000 per pound of weight gained to care for these infants in the neonatal setting. Could the argument for prevention be any clearer? In my State, $2 million would care for the needs of ail expectant mothers in that State who did not receive such care. This is the same amount of money it takes to produce one 60-minute episode of "Miami Vice."

Please give us the opportunity to continue applying the knowledge that exists today to prevent the problems of tomorrow.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. I couldn't concur more heartily in your remarks. Thank you.

[The statement follows:]

STATEMENT OF WOODROW A. MYERS, JR.

My name is Dr. Woodrow A. Myers, Jr. I am a physician and the State Health Commissioner for the State of Indiana. I am speaking to you today as a representative of the Association of State and Territorial Health Officers and the State of Indiana.

The Centers for Disease Control is an outstanding organization dedicated to developing and applying the technology and methodology needed to prevent unnecessary illness and premature death. This task is accomplished through an extremely close relationship between the CDC and State Health Departments. We work synergistically to insure that the scientific breakthroughs of the National Institutes of Health and the major medical centers around the world are effectively applied for the benefit of the American people. The importance of this task in the scheme of government is clearly at criticality one. Our prior accomplishments, and the prospects for improvement in the Nation's health are threatened by the funding cuts proposed for the FY87 CDC budget. All of us understand the importance of balancing the federal budget, but the mission of the CDC should not be placed at risk in order to achieve budget targets that are, with respect to health, somewhat illogical from the standpoint ofthe long-range savings to be achieved through prevention. The Association of State and Territorial Health Officers asks you to correct these errors, and that the mission be allowed to continue.

The Preventive Health Services Block Grant is clearly the backbone of public health. It is the only source of federal funds specified for prevention activities available to the states. Programs targeted by the Prevention Block Grant include hypertension reduction, health education, dental health , emergency medical services, and violence prevention. In the Fall of 1985, then Secretary of Health and Human Services, Margaret Heckler released her task force report on Black and Minority Health. She found that on the average, 59,000 Black American men, women and children die each year in excess of the predicted mortality if those Black men, women and children had the same mortality rates of that in the White American population. That means that today, April 24, 161 Black Americans will die, unnecessarily, because of factors either directly or indirectly attributable to race. The task force made a series of recommendations to eliminate this disparity, but no new federal funds were provided to the states to meet this challenge. In the State of Indiana we have relied on our Preventive Health Block Grant and have called together experts from throughout the state to develop strategies to improve Black and minority health. Such efforts are beginning in many other states but are sure to be aborted should the proposed cuts take effect. Such efforts are especially important in states where the proportion of low income Black and other minority citizens is high, and in states where Medicaid eligibility and reimbursement levels are low.

It is especially troublesome that the Administration has chosen to either reduce or straight-line components of the CDC immunization budget. Nowhere are the data supporting prevention activities more clear-cut: Vaccination substantially decreases disease and reduces net medical costs. Your own Office of Technology Assessment concluded that a 1983 comprehensive program using a combined vaccine for measles, mumps and rubella would have saved $387M in direct treatment costs, and paid for the vaccination program. These cost savings would have also saved 800 lives and prevented 4,000 cases of encephalitis, which is a complication of these diseases. It is short-sighted and wrong to underfund immunization when the data are so clear that investment in immunization programs significantly benefits our children and their parents.

Today there is a new vaccine available for haemophilus influenzae, an infection that can permanently disable or kill. This vaccine was developed with substantial support from the federal government, yet it is the only childhood vaccine not paid for by federal funds. At $3.00 a dose it is clearly cost-effective. Please imagine our frustration as physicians and as public health officials as we count the number of children affected by this potentially lethal disease, knowing that vials of the vaccine sit unused. Imagine the frustration of those scientists who spent years developing the vaccine, as the fruits of their labor go unused by a significant proportion of the population. It is incredible to me that we are able to mobilize our efforts in many cases to provide a necessary and beneficial $100,000 liver transplant, yet a $3.00 vaccination seemingly cannot be accommodated. This is wrong, and it is unjust. Haemophilus influenzae meningitis is a known complication of haemophilus influenzae infection, preventable by vaccination. An average hospital stay to take care of a child with this illness in the State of Indiana would cost $3,300, which in many cases will be partially reimbursed by the federal government through the Medicaid program. That $3,300 would purchase 1,100 doses of the vaccine that would have kept that child well.

Because of liability issues, the costs of many vaccines continue to increase. The CDC has experienced a 98% increase in the cost of oral polio vaccine, a 24% increase for MMR vaccine, and anticipates a 25 - 100% increase for the DPT vaccine. The CDC anticipates the need for an additional $7M for polio and MMR vaccine, and an additional $6M for DPT vaccine in 1987 to maintain state and local vaccine supplies at the 1986 level. In addition, the Administration's proposal has eliminated the vaccine stockpile that safeguards us against epidemics and production short-falls. The Association of State and Territorial Health Officers requests a minimum of $15M for the vaccine stockpile program and a total of $10M to assist in program operations at the state and local level. Members of the committee, there are so many diseases for which we can do so little. Immunization is an unambiguous opportunity to prevent disease and to save lives. What further evidence do we need to substantiate the need, the cost effectiveness, and the desirability of increased immunization?

Someone has decided that tuberculosis and diabetes control programs are no longer necessary at the federal level, for both have been eliminated from the CDC FY87 budget request. I wish I knew who that individual was, for if I did, I would invite him or her to Indiana and together we would review the recent work of a local health department when a kindergarten teacher was discovered to have a full blown case of tuberculosis. That health department's staff, in a short period of time, identified by name and location a total of 601 contacts of the kindergarten teacher, including 54 kindergarten students, 44 1st graders, 262 2nd - 5th graders, and 151 out-of-state school children. As a result of that investigation, 56 of the above mentioned contacts required preventive tuberculosis treatment and 2 cases of the disease were identified that were attributed to the contact. If caught in time, tuberculosis can be treated. If not caught in time, tuberculosis will kill. This is how we use the money provided by the CDC for tuberculosis control in the State of Indiana. This is public health in action. I would then review with that individual the reports of the American Lung Association which document a 2% increase in the number of tuberculosis cases identified last year in the United States. This study was done in Connecticut where the Connecticut State Health Department saved $81,000 last year in hospitalization costs from the money invested in tuberculosis control. A similar effort in Massachusetts saved the Commonwealth $250,000.

I would then ask that individual to review the data showing that 10 million people in the United States suffer from diabetes, but only half of those people know it. We would review the devastating complications that can result from untreated diabetes mellitus including blindness, heart attacks, and amputations and kidney failure, which frequently necessitates chronic dialysis and/or kidney transplantation. We would then count the billions of dollars that our Country spends through Medicare, Medicaid, and ' privately purchased health insurance, to treat these complications. Together we would read Secretary Heckler's report that clearly documents the disproportionate impact of diabetes on Black and minority citizens, and her recommendation that because of the "demonstrated positive impact... states should be encouraged to continue these programs". Data from successful programs in Utah, Mississippi and California have clearly demonstrated that risk-factor reduction, decreased incidence of blindness and decreased risks of major birth defects have resulted from programs funded thus far. Finally we would walk over to the Riley Children's Hospital and to the University Hospital at the Indiana University Medical Center and we would see with our own eyes the miracles that can be accomplished with early identification and treatment. Then I would again ask that individual to explain to me the logic of eliminating diabetes control from the CDC budget.

Nowhere is the work of the CDC better seen than in the area of sexually transmitted diseases. Dr. Gene Washington and many others at the CDC have now identified chlamydia as more prevalent than gonorrhea in our population. Chlamydia affects 3-4 million people every year, and contributes substantially to the incidence of infertility, ectopic pregnancy and miscarriage in our society. The CDC has promulgated guidelines for a national program, but incredibly our government has not dedicated any funding to this program that would save a substantial portion of Medicaid funds now spent to treat the effects of chlamydia infections. We need, today, a comparable federal investment in chlamydia prevention and early treatment, as was done for gonorrhea in the early 1970's. In spite of this need, the budget for sexually transmitted diseases has been straight-lined for 1987.

The final category of expenditures I wish to address is that for the Acquired Immune Deficiency Syndrome - AIDS. Although the Congress has been generous with respect to its appropriations for AIDS, the FY 87 request is not sufficient to meet the need to control the Nation's number one public health problem. Although it is quite appropriate to invest in the search for effective treatments and for a vaccine, the only weapon currently available is that of education for prevention. Virtually all of that effort stems from programs at the state and local level. It is crucial that the Congress restore funding for alternative test sites and that the Congress substantially increase funding for health education and risk reduction. In San Francisco and in New York, approximately 75% of the high risk population has already been infected with the virus, and for them, medical science and public health have little to offer, for once infection occurs, the virus replicates and is spread to others through sexual contact and blood to blood contact as it slowly kills its host. In Indiana, only 20% of our high risk population has been exposed to the virus. Thus in Indiana, and in states like Indiana, we have an opportunity to keep from becoming a San Francisco or a New York with respect to this disease. That opportunity will surely be lost if we are unable to sustain the vigorous education and prevention efforts we have started. It is unlikely that a vaccine or a treatment will be available prior to the early 1990's, but approximately 2 million people in the United States now harbor the virus and are spreading it to others. The number affected doubles each year. In every state represented on the committee, AIDS is a serious and immediate problem. We urge you to make certain that our risk reduction efforts are allowed to continue, for there is no other alternative for millions of Americans.

There is no longer a question about the value of prevention. It costs about $800 in Indiana to care for an expectant mother prior to delivery. We know that mothers that do not receive such care are three times as likely to deliver low birth-weight infants requiring hospitalization in our neonatal intensive care units. In Indiana, it costs society $18,000 per pound of weight gained to care for these infants in the neonatal setting. Could the argument for an investment in prevention be any clearer? In 1986, $2M would care for the prenatal needs of all expectant mothers in Indiana who today do not receive such care. This is the same amount of money it takes to produce one 60-minute episode of "Miami Vice". Our goals are clear and our methods are proven. Please give us the opportunity to continue applying the knowledge that exists today to prevent the problems of tomorrow.

SELECTED CATEGORIES
CENTERS FOR DISEASE CONTROL BUDGET

	FY 1986 APPROPRIATION	FY 1986 GRAMM-RUDMAN REDUCTION	FY1987 REQUEST	FY 1987 ASTHO RECOMMENDATIONS
PREVENTIVE HEALTH BLOCK GRANT	90,956	3,911	89,000	98,500
SEXUALLY TRANSMITTED DISEASES:				
Grants	46,511	2,000	45,510	58,000
Program operations	9,774	420	9,943	9,943
IMMUNIZATION:				
Grants	47,359	2,036	47,666	68,400
Program operations	8,235	354	8,346	10,000
Vaccine stockpile	4,000	172	0	15,000
TUBERCULOSIS GRANTS	5,000	215	0	5,000
DIABETES CONTROL	5,000	215	0	5,000
AIDS				
Surveillance	5,761		6,000	6,000
Epidemiology	9,002		10,020	10,020
Laboratory	3,889		3,970	3,970
Health Education/Risk Reduction	14,990		15,658	35,658
Innovative Programs	1,415		1,525	1,525
Demonstration Programs	4,465		4,622	4,622
Public Information	3,790		3,269	3,269
Alternative Test Sites	10,400		0	10,400
CDC Hotline	350		350	350
AIDS TOTAL	54,062		45,414	75,814

(000 OMITTED)

STATEMENT OF DR. CHARLES M. CLARK, JR., MEMBER, NATIONAL DIABETES ADVISORY BOARD

Senator WEICKER. The next witness is Dr. Charles Clark, member of the National Diabetes Advisory Board.

Dr. CLARK. Good morning. I am Charles Clark, and I am director of the Diabetes Research and Training Center at Indiana University and a member of the advisory board. We have submitted testimony. I am not going to repeat it. There are some things that I would like to point out.

The advisory board is a creature of Congress. We make a report every year to the state of diabetes, of care and research, mostly focused on Federal efforts. I will provide the staff a copy of this report, which just came out last week.

Our major concerns fcr this year and for being here is the NIH budget and the CDC budget. I would like to talk about each of those. During the last decade, a considerable amount of progress has been made in diabetes research, which has now practical implications. But for the last few years, the NIH budget has not been able to keep up with the opportunities.

For example, the commission, in 1976, suggested there be 20 diabetes research and training centers established. There are currently seven. The problem, primarily, are not that there is not enough people out there who could get to diabetes research centers, but there is not any funding. I speak from a personal point of view.

We are up for renewal this year. I have no trouble fighting a scientific fight and see whether we are good enough, but it is certainly very discouraging to all of us to do all of the work over the last decade and find we will be closed down because of no money. Last year, Congress suggested that the Institute be separated, diabetes and arthritis, and also suggested the cost would be about $5 million and about 36 positions to do that. No funds have been forthcoming, which means that this money has to come out of other things, like research money, in order to be able to do that.

Last year, Congress suggested that we fund about 635 grants, but the money was not made available. This year, we suggested that number be the same. We are not asking for an increase in the number of grants, but we would like for them to be fully funded. When you do an NIH grant, you are reviewed by your peers, and they suggest not only how good the research might be, but how much money should be appropriate. After that is done, they usually cut budgets. I have never seen anyone get any more than they asked for.

We then are faced with a situation currently that the budget is then cut again administrative. This is probably the right way to do it, because if you didn't do that, there would be fewer and fewer people being able to be funded. It does mean that the research efforts are getting less money than it really takes to do the work.

If the administration budget were passed, for example, perhaps at 20 percent as high, my budget would be cut in order to keep it in the budget guidelines. Our suggestion for the NIH budget is $503 million for the Arthritis Institute, and we have that in the testimony.

Now I would like to turn to the CDC. Dr. Myers, who is himself a Hoosier—we are sort of here appearing one after the other—talked very much about prevention. It does no good to be able to discover something which would cure diabetes or prevent complications if no one does anything about it. We have now, for example, treatment programs which are effective in the prevention for mortality of infants of diabetic mothers. Good programs implemented throughout the country would have a mortality rate of 1 to 2 percent.

The current mortality rate in the United States is 17 to 18 percent. That means that we could reduce by 90 percent the number of babies who are dying from diabetic mothers by the implementation of what we currently know.

We know that as a result of the early diabetes studies that we could prevent two-thirds of the cases of retinopathy. We could prevent one-half the cases of amputations. We need a CDC program, and we are asking for the same amount of money that we currently have, which is $7.4 million.

My understanding is the administration budget cuts out about $5 million of that basically all programs.

That is all.

Senator Weicker. I thank you very much.

Senator Proxmire might have a question. The reason why neither you nor Dr. Myers is getting any sort of questioning from me is that this is the message that I am trying to use on my colleagues here in the Senate and in the House, because those facts, those facts are incontravertible, and it is just amazing to me that my colleagues still can vote with great compassion for the money required to put into the defense budget on the speculation, on the speculation, that we may be in a war with the Soviet Union and that we may lose *x* number of lives if we are not prepared, while they totally ignore the facts as to what lives are being lost, what harm is occurring.

That is not a matter of speculation, this can be avoided, and they won't go ahead and give the money to do that. I don't understand it, I really don't.

Dr. Clark. I appreciate your view.

Senator Weicker. I think you make your point. I just wish the country would listen to it.

Senator Proxmire has joined us.

PREPARED STATEMENT

Senator Proxmire. Thank you, Mr. Chairman. Thank you, Dr. Clark and Dr. Myers for excellent testimony. I have been deeply impressed. I want to tell you that you have a real champion here in the chairman. If anybody can solve the very, very difficult problem of providing substantial funding in this area, Lowell Weicker is going to do it.

Thank you very much.

[The statement follows:]

STATEMENT OF CHARLES M. CLARK, JR.

I am Dr. Charles M. Clark, Jr., Professor of Medicine at Indiana University School of Medicine, Director of the Diabetes Research and Training Center at Indiana University, and a member of the National Diabetes Advisory Board. The Board was established by Congress to review and evaluate the implementation of the long-range diabetes plan and to report annually to Congress and the Secretary of HHS on recommendations for future policies, programs, and budgetary requirements. A copy of the Board's most recent annual report will be provided to the subcommittee today. The report describes the tremendous progress of the diabetes program during the last decade and the significant opportunities for future advances both in research and its application to treatment.

Diabetes is a serious disease of major proportions in the United States. For example, it is the leading cause of adult blindness. Diabetes also accounts for about 25 percent of all cases of kidney failure and 45 percent of all non-traumatic amputations in this country. In addition, people with diabetes are twice as likely as the general population to die of heart disease, and 2 to 6 times more likely to suffer a stroke. The perinatal death rate of infants of diabetic mothers is 2 to 4 times higher than in nondiabetic pregnancies.

Diabetes is also a costly disease. Costs directly attributable to diabetes are conservatively estimated at $13.8 billion annually. Included in this figure are $7.4 billion for direct medical care expenses and $6.4 billion for indirect costs due to disability and premature death. A major portion of this economic burden falls directly on the Federal government and the taxpayer through the Medicare and Medicaid programs and the direct health care responsibilities of the Veterans Administration, the Indian Health Service, the Department of Defense, and other Federal agencies. For example:

- The total costs to Medicare for End-Stage Renal Disease associated with diabetes are approximately $330 million per year.

- Approximately 40,000 people with diabetes are blind and 5,800 new cases of diabetes-related blindness occur each year. The cost to this country in associated public welfare expenses and lost income is approximately $75 million annually.

- Hospitalization costs for diabetes-related lower extremity amputations were about $300 million in 1980, which does not include rehabilitation, premature death, or disability costs. A major share of these expenses are borne by Federal health care programs.

Major advances in biomedical research supported by the National Institutes of Health have greatly expanded our understanding of the pathogenesis of diabetes. Perhaps the most exciting advances in the past year or two are in understanding the role of immune mechanisms in insulin dependent diabetes, which affects mostly children, in developing strategies for pancreas/islet cell transplantation, in clarifying the structure of the genes for insulin and the insulin receptor, and in clarifying the mechanisms of insulin action. For example, during the past year, there has been very significant progress in research related to transplantation of islet cells. These advances have reached the point that three centers in this country have initiated clinical trials involving islet transplants in patients with advanced diabetes who already are receiving immunosuppression for maintenance of kidney grafts. These initial studies have clearly demonstrated partial function of transplanted islets in the majority of recipients. Additional centers are conducting studies to define the effects of immunosuppression on islet engraftment and function and to improve the quality and quantity of islet tissue for transplantation.

Research related to noninsulin dependent diabetes, which affects mostly adults, also is progressing. For example, techniques of modern molecular biology are allowing detailed elucidation of the structure of key genes, in particular the insulin gene and the insulin receptor gene. This research will increase our understanding of how insulin controls carbohydrate, lipid, and protein metabolism and what causes the insulin resistance characteristic of noninsulin dependent diabetes.

These and many other advances offer significant hope that the tragic human costs and major economic burden associated with this disease can be significantly reduced in the coming years if existing diabetes research programs are maintained and strengthened. Diabetes research is clearly cost effective. The accomplishments of the past decade have already provided improved treatment strategies whereby blindness, amputations, and perinatal mortality can be reduced, saving hundreds of millions of dollars annually. However, future advances will not occur without adequate support for diabetes research programs.

Most of the recent advances in the prevention, treatment, and control of diabetes are a result of increased Federal support for biomedical research during the mid and later 1970s. This impetus has not been maintained in the 1980s, since funds for these programs have not kept pace either with inflation or with the increased opportunities for research advances. For example, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the lead institute for diabetes research, has historically funded approximately 45 percent of approved, scientifically meritorious research applications. The award rate will decline to about 25 percent in 1986 and would have been lower if the budgets of previously awarded grants had not been administratively reduced below recommended levels.

The Board recognizes that Federal resources are not infinite. However, the continuation of recent funding trends, in our opinion, will lead to the following results:

- We will lose a major opportunity to reduce the burden of diabetes if we do not take advantage of promising research opportunities that could lead to the prevention and cure of diabetes, including research related to the role of the immune system in the initiation of diabetes and the use of pancreatic islet transplantation to correct the basic diabetic condition.

- We will lose an entire generation of future basic and clinical research investigators, as bright young trainees become discouraged by both the limited number of fellowships and career development awards and the reduced likelihood of receiving research support following their training.

- Research projects already approved and funded will be severely hampered because of the large budget reductions that are being imposed upon all NIH research projects.
- The leadership of the national diabetes program will be severely hampered by reductions in the number of Federal personnel. For example, the staff of the National Institute of Diabetes and Digestive and Kidney Disease has been reduced by 70 positions in the past 18 months, and additional reductions are anticipated.

Diabetes research programs should be strengthened, not reduced. The accomplishments of the past decade provide evidence that the Nation will benefit from a strong national diabetes effort. Therefore, the Board has provided budget recommendations for the major Federal agencies participating in this program (table 1).

Table 1

BUDGET RECOMMENDATIONS FOR DIABETES-RELATED RESEARCH PROGRAMS*
(Millions of Dollars)

National Institutes of Health	1986†	1987
NIDDK	109.5	121.0
NHLBI	20.5	22.0
NEI	23.2	26.0
NICHD	11.9	13.0
NINCDS	4.7	5.5
NIAID	5.9	7.0
NIA	2.2	2.2
NIDR	4.9	5.0
NIGMS	1.1	1.2
NIEHS	.3	.5
DRR	15.5	17.0

*Amounts are only for diabetes-related activities only. However, the Board recommends a total budget of $503 million in FY 1987 for the National Institute of Diabetes and Digestive and Kidney Diseases.

†Original 1986 congressional appropriation.

The Board recommends a funding level of $503 million for the National Institute of Diabetes and Digestive and Kidney Diseases. NIDDK is responsible for planning and implementing a comprehensive national diabetes research program. It also is the major source of support for training in diabetes-related research disciplines. Special programs of the Institute include the Diabetes Endocrinology Research Centers, the Diabetes Research and Training Centers, the Diabetes Control and Complications Trial, the National Diabetes

Information Clearinghouse, and the National Diabetes Data Group, all described in our annual report. The Board's budget will enable the Institute to fund approximately 33 percent of approved individual research grants at the levels recommended by the scientific review committees, support diabetes centers at recommended levels, restore manpower development awards to the 1985 level, fully fund phase III of the Diabetes Control and Complications Trial, and enable the Institute to recruit key staff members.

Many other NIH Institutes and Divisions support diabetes-related research. The Board's budget recommendations (table 1) contain funds for these programs. Included are those of the National Heart, Lung, and Blood Institute (cardiovascular consequences of diabetes), National Eye Institute (ocular complications of diabetes), National Institute of Child Health and Human Development (effects of diabetes on pregnancy and infants), National Institute of Allergy and Infectious Diseases (infections and immunogenetic factors in diabetes), National Institute of Neurological and Communicative Disorders and Stroke (neurological complications of diabetes), National Institute on Aging (interrelationships between diabetes and aging), National Institute of Dental Research (dental complications of diabetes), National Institute of Environmental Health Sciences (relationship between environmental agents and pancreatic structure and function), and National Institute of General Medical Sciences (the training of physician-scientists). In addition, the General Clinical Research Center program of the Division of Research Resources supports noncategorical clinical research facilities in which the vast majority of all clinical investigations related to diabetes are conducted. All of these programs should receive additional funds for their diabetes-related research activities.

The Board also recommends funds to continue the national Diabetes Control Program of the Centers for Disease Control (CDC). This agency has developed a national strategy to apply current research advances to the prevention of some of the complications of diabetes. Working with state agencies, the CDC has developed cost effective programs that already have reduced diabetes-related hospitalization costs in selected project areas. The Board strongly recommends that the CDC program receive $7.4 million in fiscal year 1987, the same level Congress provided in fiscal years 1985 and 1986.

STATEMENT OF PATRICIA SCHULTZ, R.N., FLORIDA DIABETES ADVISORY COMMITTEE

Senator PROXMIRE [presiding]. The next witness is Patricia Schultz. You are also testifying on diabetes?

Ms. SCHULTZ. Yes, sir.

Senator PROXMIRE. Go ahead.

Ms. SCHULTZ. Mr. Proxmire, I am very pleased to be here. I am excited about being here, and I am even a little nervous about being here to speak with you for a few moments on a subject of great importance to 12 million people in the United States 24 hours a day with diabetes. Can you hear me?

Senator PROXMIRE. Yes.

Ms. SCHULTZ. First, allow me to introduce myself. I am currently involved in the clinical care of people with diabetes. I am chairman of the Florida Diabetes Advisory Council, past vice president of the National American Diabetes Association, nationally representing health care professionals across the country.

During my 20-year commitment to improved diabetes care—and I am sure you couldn't have guessed that, I look much younger——

Senator PROXMIRE. You certainly do. You are 20 years old? [Laughter.]

Ms. SCHULTZ [continuing]. I have witnessed personally many tragedies caused by the complications of diabetes. I was at the bedside 13 years ago of a child that developed diabetes. She is totally blind due to diabetes and has end-stage renal disease because of that disease. Each year, diabetes debilitates thousands of Americans. We note, for example, that diabetes is the leading cause of new cases of blindness in this country in adults. We are talking about nearly 6,000 people newly blinded every year because of diabetes, and the disheartening and yet the exciting thing I share with you is most of those cases of blindness are preventable if detected early.

This is an area in which we really truly can do something. In Florida, for example, as one of the 10 federally funded retinopathy projects, we will be screening 2,000 indigent persons with diabetes. We are looking for those early signs of retinopathy, which is a dreaded complication of diabetes. These people are people that otherwise would not have access to an ophthalmologist. Further, if we prevent one case of blindness, we will more than pay for the project in our State in avoiding the medical cost, the cost of rehabilitation, and future welfare costs.

In terms of lost income and public welfare expenses, the most is estimated to be $785 million in the United States just due to blindness. There are so many other complications associated with diabetes.

For example, it causes about one-half the amputations, only secondary to trauma, and a major share of that $300 million that will be spent because of amputations assumed by the Federal health care programs.

Additionally, diabetes accounts for approximately all the cases of kidney failure. Federal funds again paid the majority of that $280 million per year; the cardiovascular applications; the outcomes of pregnancy

Dr. Clark alluded to; the list goes on and on. Time doesn't allow me to go on and on.

To change the systems of the way people manage diabetes, which is an extremely complicated disease, all take time. What we have done is we have identified problem areas. We have found ways to effect changes and ways to translate the research into the clinical practice. All too often, we see medical care has not kept in tune with the current state of the art with respect to diabetes treatment and management.

Public health, in concert with diabetes organizations, has a crucial role, indeed, to facilitate networking and to interface to affect the educational programs which will ultimately benefit the person with diabetes. What we want to do publicly is to speed up that process, take the research and work quickly into community practice, take this network that has been established and apply it to specifice complications of diabetes, real application of the hard problems related to diabetes. The retinopathy project that I mentioned previously is an example, but we need to further emulate that approach with regard to amputations, kidney disease, adverse outcome of pregnancy, keto acid doses, et cetera.

A final highlight: In the face of having the $5 million for cooperative agreements for States with diabetes control activities and the assigned public health advisors cut, we are in jeopardy of tremendous losses. We need the funds to take us well beyond the demonstration phase. Funding will, in fact, provide the mortar, if you will, to put together the bricks and the structure that has already been created to date. We are on the brink of having an ever-escalating impact of diabetes health care.

On behalf of the diabetes advisory boards of the State diabetes control projects, we urge that the program be maintained in fiscal year 1987 at the level that Congress did provide in 1985 and 1986; in other words, restore the $5 million that the administration has proposed be eliminated. I know that beyond the shadow of the slightest doubt that this request is genuine, that it is above approach and that yours is a task to respond. We trust and believe that your deliberations will be placed on your constituents' needs and the commitment to the enhancement of our public's health.

Senator PROXMIRE. Ms. Schultz, you argue that this program is cost effective.

Ms. SCHULTZ. Yes, sir.

Senator PROXMIRE. I think the case you make is very convincing. Have you had a lot of experience in Florida with the State operation.

Ms. SCHULTZ. Yes, sir.

Senator PROXMIRE. Do you think the States should or could assume responsibility for the Diabetes Control Program in view of its cost effectiveness? In other words, since it would reduce State costs, as you say, could the States pay for this program?

Ms. SCHULTZ. I think the States are probably in the same position that the Federal Government is in: the throes of cuts. We, in our particular State, have our diabetes adviser counsel that does work very closely with the control project. I think that we have an augmented effect where we are putting the two efforts together.

I think our State is not in a position to take over what the Diabetes Control Program is doing. However, we are not one of the project States. We only have one of the assigned public health advisers to our area, and he has made a tremendous impact and has made things happen in the few months that we have had him on board.

Senator PROXMIRE. Is your State putting more funding into the program than it did before?

Ms. SCHULTZ. The State?

Senator PROXMIRE. The State of Florida, I am talking about.

Ms. SCHULTZ. Yes, yes; we have. And we are up for going to Congress again.

PREPARED STATEMENT

Senator PROXMIRE. Very good. Thank you very much. We appreciate your help.

Ms. SCHULTZ. Yes, sir.

[The statement follows:]

STATEMENT OF PATRICIA SCHULTZ

Mr. Chairman and members of the Committee, thank you for the opportunity to speak to you for a few moments on a subject of great importance to the twelve million Americans who live with diabetes. I have come before you to request you consider several important points when you determine funding for the Diabetes Control Program of the Centers for Disease Control.

First, let me introduce myself, my name is Patricia Schultz. I am currently involved in the clinical care of people with diabetes. I am the Chairperson elect of the Florida Diabetes Advisory Council and past Vice-President of National American Diabetes Association, and I am a member of Florida's State Affiliate.

As the Committee heard last year, diabetes is a leading cause of death and disability in the U.S. It is the leading cause of new cases of blindness in people ages 20-70 years, approximately 5,800 people will become legally blind from diabetes each year. The cost in terms of lost income and public welfare expense is estimated to be $75 million annually.

Diabetes is responsible for 40-45% of the nontraumatic amputations in the U.S. Only about 50% of diabetics who suffer an amputation survive 3 years or more.

The risk of death to the fetus of a diabetic woman is 2-7 years higher than in the non-diabetic population. The risk of congenital malformation is also higher.

Diabetes accounts for approximately 25% of the cases of kidney failure in the U.S. Federal funds from Medicare pay the majority of costs for renal dialysis for these individuals. The cost to Medicare of diabetic kidney failure is estimated at over $280 million per year.

Since 1977, CDC's Diabetes Control Program has been a leader in the fight to control diabetes. CDC has participated in the development of national consensus on the diagnosis and care for diabetes and most importantly, prevention and treatment of complications. In addition, and perhaps more importantly, CDC has developed mechanisms which have allowed for rapidly translating new advances, including CDC project findings into community practice.

These efforts have resulted in the demonstration of effective private and public health care efforts to detect and treat complications and reduce costs. For example, in Mississippi, 11% of those attending a screening to detect diabetic eye disease were found to have conditions which would lead to blindness. Treatment of these individuals saved their sight.

In New York state, a demonstration project showed a decrease in amputations and associated costs among a group of high risk patients. A similar control group not in the project suffered 6 amputations in the same time period.

In South Carolina, deaths of babies of diabetic mothers were reduced by almost 50%.

A demonstration project in California reduced congenital anomalies by 60%.

In Utah, improvement in the delivery of health care to Ute Indians (a group at high risk for diabetic-related kidney failure) led to an average 20% improvement in blood glucose and blood pressure was controlled in 77% of the diabetic Indians.

Just at the time when the Diabetes Control Programs have developed a base from which they can extend these achievements to a broader population, it faces virtual destruction in the field operations which are the most crucial for effective outreach to the community. The $5 million for state operations must be restored to this budget; the 20 public health advisory positions must be maintained for this work to go beyond the demonstration phase to benefit people with diabetes throughout the country.

STATEMENT OF GARY B. McDONALD, EXECUTIVE DIRECTOR, AIDS ACTION COUNCIL

Senator Proxmire. Our next witness is Gary McDonald, executive director, AIDS Action Council. Mr. McDonald, it is good to have you here.

Mr. McDonald. Senator, it is a pleasure. It is a privilege to testify before you today. I am Gary B. McDonald, executive director of AIDS Action Council, a group that represents 110 community-based groups around the country working with people with AIDS, their loved ones, and the larger communities that fund them.

I would like to commend you, Senator, and other members of the committee for your commitment over the years to Federal AIDS-related funding and particularly for doubling the AIDS-related appropriation from 1985 to 1986 and for refusing just 1 week ago to permit the administration to slash funding for this legislation during this crucial time.

In large part, due to the work of this subcommittee, Senator, we have come a long way in the last year, particularly in our understanding of AIDS, but we are still on the ground floor of this crisis.

Despite the remarkable progress, I think that this society does not yet fully comprehend that AIDS is a long-term reality in this country which requires long-term commitments of funding and determination from all of us. More than 1 million men, women, and their children are asymptomatically affected with the virus that is believed to cause AIDS, and perhaps by some studies, as many as 500,000 of them will develop some illness in the spectrum of HTLV–III infection and require the complex matrix of services that even now, for far fewer people, is taxing the health care delivery system. We need a plan, Senator. We need a comprehensive and detailed Federal plan of attack on AIDS. We don't have it yet. It is not simply enough to state goals. We have got to say how we are going to achieve those goals. Addressing the long term will require not only a lot of money, but also the consistently wise use of those scarce resources. They get scarcer all the time.

The council urges you, Senator, and the rest of the subcommittee, to reject what we believe to be the unwise proposal by the administration to concentrate all fiscal 1987 AIDS-related appropriations in the Office of the Assistant Secretary for Health. This proposal would deprive Congress of its right to designate specific appropriations for specific purposes. It would also make sequestration more feasible.

In regard to next year's, that is, the 1987 appropriation, Senator, I would urge the subcommittee to pay careful attention to the documentation from the Public Health Service agencies that suggest the need for perhaps as much as $400 million in overall AIDS funding. A great deal more is required for the science of AIDS. We are on the verge of breakthroughs. To deny scientists the flexibility of funding and particularly the personnel they need right now to bring these projects quickly to fruition would be truly penny-wise and pound-foolish.

We also need to study much more fully the full spectrum of disease caused by this virus. AIDS is a rarity in that spectrum.

With regard to psychosocial aspects of the disease, we need to increase the study of the largely negative impacts that this virus has had on our society. The unquestionably grim reality of AIDS has driven many of us not toward unity and empathy, but rather toward recrimination, fear, and denial. Of principal concern must be how the society will deal wisely and humanely with hundreds of thousands of affected but asymptomatic citizens.

AIDS health care remains the single most costly and inadequately managed aspect of this crisis. A bill has been recently introduced by Senator Kennedy with many other sponsors. We would like to work very closely with you in making that a good bill with regard to health care.

Finally, and most importantly, as others have already pointed out, we need far larger appropriations for AIDS education and prevention activities. These are our only lines of defense against this disease presently. The money for those programs should not be taken away from other equally vital research and education programs, primarily sexually transmitted diseases [STD] programs.

We need to concentrate, in conclusion, on physicians, health care workers, educators, public officials, adolescents, minorities, and intravenous drug users, principally. That is a long list, Senator.

Thank you very much.

PREPARED STATEMENT

Senator PROXMIRE. I think that was an excellent presentation. I deeply appreciate it. You certainly make a persuasive case. We will try to do something.

Mr. McDONALD. Thank you, Senator.

[The statement follows:]

STATEMENT OF GARY B. MACDONALD

Mr. Chairman and distinguished members of the Subcommittee, it is a privilege to testify before you today. I am Gary B. MacDonald, executive director of AIDS Action Council, an organization representing more than 110 community-based groups throughout the U.S. which provide services to People with AIDS and AIDS-Related Complex and their loved ones, and educate all sectors of the public about this terrible disease.

The Council commends you, Mr. Chairman, and the other members of the Subcommittee for your steadfast commitment over the years to Federal AIDS-related funding. You recognized and acted to resolve this urgent crisis long before the public or private sectors, or Americans in general, understood the necessity for action. I particularly commend you for voting to double AIDS-related funding from 1985 to 1986, and for refusing just a week ago to permit the Administration to slash funding for AIDS research and education at this crucial time. When the history of this epidemic is written -- and let us pray that will be soon -- you will be remembered as far-sighted legislators serving America's health interests in the best tradition of compassionate public service.

Your commitment has helped bring the Federal government, the scientific establishment and this society a long way in the past twelve months toward understanding AIDS. Errors of omission and commission have been made by all of us in the process, but the Council is not concerned now with mistakes of the past. Today we will focus on the challenges of the future.

Despite the progress that has been made on scientific, medical, educational and social fronts, Mr. Chairman, our society does not yet fully comprehend that AIDS is a long-term reality in this country which requires long-term commitments of funding and determination from all of us. AIDS is now one of the leading killers of young men in America, and even if a vaccine were available tomorrow, those young men would continue to die in increasing numbers because of infections contracted previously. More than a million men, women and children are asymptomatically infected with the virus that is believed to cause AIDS. Perhaps as many as 500,000 of them will eventually develop some presentation of illness in the spectrum of HTLV-III infection, and require the complex matrix of services that, for far fewer people now, is already taxing the health-care delivery system. A year ago when I testified before you, 10,000 cases of AIDS had been reported. Today that number is almost 20,000. Next year at this time it will be 40,000, and rising.

Clearly, to act responsibly today in the interests of the future requires that we sit down -- legislator, bureaucrat and citizen alike -- and develop a comprehensive plan. Even as we speak, however, no such plan exists. Its absence creates a policy vaccum in which decisions about AIDS that have serious medical, legal and social consequences are being made piecemeal at all levels of Federal, state and local government.

The Council urges you, Mr. Chairman, to put teeth into a reiteration of your past request that the Public Health Service develop a comprehensive and detailed Federal plan of attack on AIDS. It is not enough merely to state goals; the Public Health Service must also tell us how those goals are to be achieved.

Part of the problem is lack of permanent personnel to direct the planning. An Assistant Secretary for Health must be nominated immediately, and a Public Health Service Coordinator for AIDS named. Once appointed, these individuals must move quickly to strengthen and consolidate the good work already being done. They must also carefully analyze short-term priorities in the context of long-term needs.

Addressing the long-term will require not only a great deal of money over an extended period of time but also, more importantly, the consistently wise use of those scarce resources. The Council urges you, Mr. Chairman, to reject what we believe to be the unwise proposal by the Administration to concentrate all fiscal 1987 AIDS-related appropriations in the Office of the Assistant Secretary for Health. Lacking permanent staff, a detailed plan of action and a commitment from the Secretary himself for staff and resources to implement it, this proposal could not work even in theory. Practically, it would deprive Congress of its right to designate specific appropriations for specific purposes. It would also increase the ease with which the Administration could sequester funds and delay progress, as has already happened this year, in order to satisfy political rather than scientific priorities.

In regard to fiscal 1987 AIDS appropriations, the Council strongly urges you, Mr. Chairman, to consider carefully the documentation from Public Health Service agencies that suggests the need for at least $400 million in overall AIDS funding next year. The following are priority concerns:

THE SCIENCE OF AIDS. Between $60 and $80 million in funding beyond the current base level is required by the National Institutes of Health to expedite significant recent progress in vaccine research, clinical trials of anti-viral and immune-stimulating drugs, studies involving genetic modeling and protein synthesis and the development of diagnostic devices. Scientists are on the verge of breakthroughs in all of these areas. An anti-AIDS vaccine, for example, is much closer to realization today than it was even six months ago. To deny scientists the flexibility of funding, and particularly the personnel, they need right now to bring these projects quickly to fruition would be truly "penny-wise and pound-foolish."

Significant additional funding is also required to study the full spectrum of disease caused by the HTLV-III virus. Disturbing new discoveries about the neurological impact of infection must be investigated. Research now confirms that many more people will suffer from AIDS-Related Complex, neurological and other complications of infection than from AIDS itself. We must learn quickly how this infection behaves in all of its presentations, as well as how those presentations are linked and may be treated effectively so that full-blown AIDS remains what it is today -- a rarity.

THE PSYCHOSOCIAL SCIENCE OF AIDS. In addition to studies of the disease itself, increases of between $10 and $20 million beyond current base levels of funding are required to study the profound and so far largely negative impact AIDS and HTLV-III infection have had upon our society. The unquestionably grim reality of AIDS has driven much of the population not toward unity and empathy, but rather toward recrimination, fear and denial. While these extreme reactions may be understandable, they also enhance the suffering and stigma associated with this disease and may actually encourage the spread of a virus whose transmission thrives on ignorance.

Scientists urgently need to examine the psychological implications of HTLV-III infection that may or may not progress to presentations of illness -- the implications not only for the infected individual but also for his or her surrounding community. A principal concern must be how this society will cope wisely and humanely with hundreds of thousands of infected but asymptomatic citizens. Effective modes of counselling and social support must be developed and implemented. The social and psychological impact of a sexually transmitted disease that primarily affects citizens perceived to be "outside the mainstream" must also be studied. Without such firm scientific underpinnings, we risk the institutionalization of fear by default -- a fear that has already begun to erode the compassion and good sense that have traditionally made America exemplary among nations.

HEALTH-CARE ASPECTS OF AIDS. Four health-care demonstration projects about to get underway in cities where incidence of infection is very high must be augmented in 1987 with between $10 and $20 million additional funding to mount similar projects in areas of the country where infection is not so widespread. Again, attention to the long-term demands that we study the needs and capabilities of states and cities which are not now equipped to handle even one case of AIDS, let alone hundreds.

AIDS EDUCATION AND PREVENTION. Finally, and perhaps most important, is the need for far larger appropriations for AIDS education and prevention activities. These are our only line of defense, both now and for years to come, against the spread of HTLV-III infection. To slight education now, or to conduct prevention programs with inadequate resources, is to guarantee that AIDS will be with us for a generation.

The Council believes the current appropriation for AIDS education and prevention must be increased in 1987 by a minimum of $30 million. This level of additional funding is vital to ensure that all 50 states, not just 25 or 30, are capable of educating their at-risk and no-risk populations alike.

Because disturbing instances of AIDS-related ignorance continue to characterize physicians, health-care workers, educators and public officials throughout the country, these professional groups must also get immediate enhanced support.

Particular "windows of opportunity" for transmission of the HTLV-III virus, and simultaneously for stopping its transmission, are now clearly evident in minority communities and among adolescents and IV drug-users. For various reasons these populations are at very high risk of infection because they so far lack the skills to prevent it. Increased funding would focus attention on programs to give them those skills.

While the gay community has achieved remarkable success in educating its own as well as the non-gay public about AIDS, it cannot continue to do so without significantly increased Federal assistance. This highest-risk of all risk groups, which has privately raised millions of dollars since 1981 to pay for education, prevention and services for all citizens, cannot continue to bear the burden virtually alone.

The Council would point out in conclusion, Mr. Chairman, that the current policy of administering Federal AIDS education and prevention programs in one Public Health Service agency and funding those programs by means of grants primarily to and through state public health departments may not be as effective as it could be. More than one Public Health Service agency has statutory authority to conduct education programs; all have expertise to contribute. Moreover, any public or private organization -- not just public health departments -- that is capable of demonstrating expertise and ability should be eligible to compete for a much larger proportion of Federal AIDS education and prevention dollars than is now possible.

STATEMENT OF WENDY J. WERTHEIMER, DIRECTOR OF PUBLIC AND GOVERNMENT AFFAIRS, AMERICAN SOCIAL HEALTH ASSOCIATION

Senator PROXMIRE. Next we will hear from Wendy Wertheimer. Are you related to Fred Wertheimer?

Ms. WERTHEIMER. Fred claims to have no living relatives.

Senator PROXMIRE. That is his loss.

Ms. WERTHEIMER. The Federal programs of sexually transmitted diseases prevention and control over the past several years have suffered a cut in funds, a reprogramming, a hiring freeze, the Gramm-Rudman sequestration and in the past fiscal year, the direct diversion of a substantial portion of its funds and personnel to AIDS activities. These events have had devastating impact on the health of the Nation, especially on young people, on women, and babies.

In hearings last year before this subcommittee when a $1.5 million reprogramming was requested, many members of the committee said: Is this all you are going to need to reprogram? And we said: Yes; we don't need to reprogram any more money from the STD Program. We have quite enough in AIDS, thank you.

In fact, by the end of the last fiscal year, up to 30 percent of the STD Program was being diverted to AIDS activities. Although there are only two diseases that the STD Program has made a substantial amount of funds available for, these two diseases are alsc lost from our control right now. Although it is the common wisdom that because everybody is so afraid of AIDS, they think the other STD's are going down, that is not true.

In fact, gonorrhea increased almost 7 percent nationwide. That is the first increase in 5 years, the first increase in rates in a decade. Syphilis is coming down. We still have some control of syphilis. That is mainly because the gay community has changed its behavior. In fact, syphilis in babies has gone up 100 percent in the last fiscal year, probably.

Senator PROXMIRE. You say syphilis in babies has gone up 100 percent. What does that mean?

Ms. WERTHEIMER. Very tiny numbers.

Senator PROXMIRE. You say the numbers are small?

Ms. WERTHEIMER. Two hundred or three hundred cases of congenital syphilis has gone up to 300 or 400 cases. It is still small numbers, but there shouldn't be babies in this country with syphilis.

Senator PROXMIRE. Are there countries with no babies with syphilis?

Ms. WERTHEIMER. China, probably. But gonorrhea is on the increase again. That is very frightening, because gonorrhea's resistance to antibiotics is increasing. There has been a fourteenfold increase of gonorrhea.

Senator PROXMIRE. What is the incidence of gonorrhea?

Ms. WERTHEIMER. The incidence of gonorrhea is over 1 million cases reported in 1 year. It is probably several times more than that, in fact. Every State has resistant gonorrhea now. It increased 70 percent in the last fiscal year, alone. When you are taking money away from doing the kinds of controls that we can do in syphilis and gonorrhea and putting it into AIDS, it is a very dangerous precedent to set. You can see what happens. The rates still go up.

There are other diseases we can't even begin to touch, like a disease you are quite familiar with by now, chlamydia, thanks to report language from this committee directing CDC to do more in chlamydia. We are hoping something more can be done. The fact is chlamydia infects more than 4 to 5 million Americans a year; it has devastating impacts on women; for women it can lead to sterility and ectopic pregnancies. More than 100,000 babies are affected by chlamydia every year.

Herpes sufferers, there are more than 20 million. Human papilloma virus, which nobody has begun to talk about, is probably the most prevalent sexually transmitted disease and probably has an association with cervical cancer. Seven thousand women a year die of cervical cancer.

These are diseases that are being lost while all the attention is paid on AIDS, and the attention being paid on AIDS is appropriate. That is the kind of effort that we need to deal with communicable, sexually transmitted diseases. The other diseases, unfortunately, are being dangerously left behind, and as we turn our attention away from them, they are only going to rise.

Ectopic pregnancies, in 1981, there were 17,000 in this country. The most recent figures I have are 1983, when there were more than 7,000 ectopic pregnancies. Ectopic pregnancy is the leading cause of maternal death among black women and probably one-half of those ectopic pregnancies are directly related to sexually transmitted disease.

So, Mr. Chairman, I hope that some effort will be made to restore the money that has been directed away from sexually transmitted diseases to AIDS; that all money possible will be given to AIDS, but that we have to recognize that sexually transmitted diseases are the No. 1 public health emergency in this country.

They are killing women. They are killing babies. They are preventing young people from having any reproductive health in the future, and we are just trading lives for lives, because we are going to lose women and babies, and we are sacraficing fertility, and we have to deal with all of them and not just one. It is estimated that $50 million are necessary to perform chlamydia control nationwide. I think that is a small price to pay to deal with a disease that is affecting 5 million people every year.

Senator PROXMIRE. Thank you, Ms. Wertheimer. That is very impressive testimony, and I think your comments will surprise many people because they have focused on AIDS, which, as you say, deserves our attention.

Ms. WERTHEIMER. That is the way we should be dealing with everything.

Senator PROXMIRE. You say that we should be more vigorous. Some feel the funding provided for AIDS is inadequate.

You make the statement that the No. 1 public health problem is sexually transmitted diseases, including AIDS. That is a startling and a shocking statement. I want to make sure I understand where you are coming from because that does seem an exaggeration. Most people would say heart disease or cancer, which take more lives, perhaps, constitute a greater problem and should take more funding.

Ms. WERTHEIMER. True.

Senator PROXMIRE. Many believe that they constitute a greater threat to human life than sexually transmitted diseases. Do you dispute that?

Ms. WERTHEIMER. I would back my statement up by saying that these are diseases which are continuing to spread. These are communicable diseases, and they are uncontrolled, and this year, CDC says there are 12 million new cases of STD's every year. We are not controlling those diseases, and chlamydia is uncontrolled. This year we have 5 million cases of chlamydia. Ten years from now, we are going to have more cases of chlamydia. It is going to grow exponentially.

The difference between these diseases and others is that these are spreading. It is not well recognized the effect that these diseases have on babies, on ectopic pregnancy, on future cancer. They are two factors in a lot of other problems. It largely has been unattended to and largely ignored.

I think that we are very aware of cancer and heart disease and a lot of the other problems, but the fact is that people continue to ignore sexually transmitted diseases.

PREPARED STATEMENT

Senator PROXMIRE. There is a moral problem involved, as you all know, which has frustrated, unfortunately, treatment in all these sexually transmitted areas.

Thank you very much. I think your statement was most expressive and very useful.

[The statement follows:]

STATEMENT OF WENDY J. WERTHEIMER

Mr. Chairman, on behalf of the Board of Directors and members of the American Social Health Association, one of the oldest non-profit organizations in the country, I appreciate this opportunity to speak to you on behalf of Fiscal Year 1987 funding for the Division of Sexually Transmitted Diseases of the Centers for Disease Control.

ASHA, founded in 1912, is unique in that we are the only national non-profit organization solely focused on the epidemic of sexually transmitted diseases. Our programs include the VD National Hotline, the Herpes Resource Center, the Venereal Diseases Research Fund, as well as professional and public education initiatives.

Mr. Chairman, the federal program of sexually transmitted diseases prevention and control has been devastated over the past few years by the sheer magnitude of the STD problem, a cut in funds, a reprogramming, a hiring freeze, the Gramm-Rudman sequestration, and the direct diversion of funds and personnel to AIDS activities. These events have had a severe impact on the health of our nation, particularly young people, women and their babies.

In hearings before this Committee last year, the Centers for Disease Control testified that, apart from a requested $1.5 million reprogramming from the STD program for AIDS, no further diversion of funds would be necessary. Report language requested written notification to the Committee of any other diversion of funds. Yet by the end of FY 1985 up to 30% of STD funds were being diverted to AIDS, with an average over the year of 15% of the program funds diverted. In addition, 45 FTEs were diverted to AIDS activities.

No written notification of this significant diversion of funds and personnel was ever sent to this Committee. Further, this diversion clearly violates the intent of Section 318 of the Public Health Service Act authorizing the program. That legislation provides that STD funds may be made available to AIDS activities after appropriations for STD grants to states exceed $50 million in FY 1985. One-half of the excess over $50 million can be made available for AIDS. In FY 1986, one-half of the excess over $52.5 million may be made available for AIDS, and in

FY 1987, one-half of the excess over $55 million shall be available for AIDS activities. As you well know, Mr. Chairman, funding for grants did not nearly approach the threshholds provided in the legislation.

This is in no way a suggestion that any less funding or attention should be devoted to AIDS. In fact, Mr. Chairman, we support and endorse whatever federal funds are necessary to deal with AIDS. However, this funding and personnel should not be at the expense of a program which must also deal with epidemics which are out of control. The Administration's policy of funding AIDS at the expense of other sexually transmitted diseases is unwise, short-sighted, and dangerous.

CDC estimates that approximately 12 million Americans will acquire a sexually transmitted disease this year — among them 2.5 million teenagers. Through FY 1984 fully 94% of the federal STD control program was devoted to syphilis and gonorrhea control. However, at least 20 organisms are known to cause sexually transmitted diseases, including Chlamydia Trachomatis, herpes simplex viruses, cytomegaloviruses, hepatitis B, human papilloma viruses, and HTLV-III. Infections caused by these organisms have devastating impact on reproductive health, maternal and child health, neonatal health, and neoplasia. Despite dramatic increases in these infections, the only one of these diseases receiving strong federal attention is HTLV-III. Virtually no control effort is taking place for the other diseases, diseases which are not only dangerous but sometimes deadly as well. Tens of millions of Americans are affected by the other sexually transmitted diseases, yet no new initiatives have been undertaken, and the STD program can accord them only minimal attention. Budget constraints have made difficult and terrible choices necessary. We are trading lives for lives.

Gonorrhea: Gonorrhea remains the most commonly reported disease and represents the largest investment of STD control efforts. Reported cases of gonorrhea have been decreasing steadily for most of the past decade. However, in FY 1985, when funds were diverted away from the program, reported gonorrhea morbidity increased for the first time since 1980. Further, in addition to gonorrhea cases increasing by 6.8%, gonorrhea rates increased for the first time in a decade.

Additional obstacles confront efforts to control gonorrhea. From 1979 to 1984 there was a 14-fold increase in gonorrhea resistant to antibiotics. In FY 1985 the number of reported cases of penicillin-resistant gonorrhea increased 70%. Antimicrobial resistance severely hampers efforts to control the disease.

Syphilis: Until 1983 syphilis rates were increasing steadily, however since that time, due to changes of behavior among gay men, rates of primary and secondary syphilis have decreased. However, syphilis remains a problem in the heterosexual community, and with further program diversion the rates of syphilis can be expected to rise once again.

It is extremely distressing to note that although overall syphilis has decreased during the past two years, congenital syphilis has shown a large increase in the past fiscal year. In 1980 congenital syphilis rates reached their lowest point, but since then have steadily risen. In 1985 alone, congenital syphilis in infants increased 70%. Rates of congenital syphilis rose 100% between FY 1984 and FY 1985.

Thus the STD program, which had had some sucess in past years in controlling both syphilis and gonorrhea has now failed to maintain control even of those two diseases in which it has the greatest investment of funds and energies. Yet this program is being further burdened by added responsibility for AIDS surveillance, HTLV-III testing, and health education and risk reduction projects for AIDS. But the program has never received any additional funds to carry out these important functions. These demands have made impossible any progress in the control of other STDs which demand attention and commitment.

Chlamydia: Chlamydia is the most common bacterial sexually transmitted disease in the United States today, causing infections in men, women, and babies. It is several times as prevalent as gonorrhea. CDC estimates that more than 3 million cases of chlamydial infection occur each year. In men chlamydia causes non-gonococcal urethritis. In women, the consequences of chlamydial infection can be devastating, resulting in sterility or ectopic pregnancy. Chlamydia can be passed on to babies of infected mothers, causing eye problems and pneumonia in more than 100,000 infants annually. Pregnant women with chlamydia may have a greater risk of miscarriage or stillbirth. Between 7 and 12 percent of all pregnant women are estimated to be infected with chlamydia.

Diagnostic tests are now available which can detect chlamydia quickly and inexpensively. These tests would permit diagnosis of this hidden epidemic disease which is also treatable and preventable. Yet no national chlamydia control initiative has been possible, due to budget constraints. The President's budget would make such a program impossible. CDC has funded a cooperative agreement and demonstration projects to determine control strategies. It is a tragedy that a disease which affects so many lives, which is largely asymptomatic, but is preventable has not received federal attention because of lack of funds.

Herpes: At least 20 million Americans suffer from genital herpes virus infections, with approximately 600,000 new cases each year. Since 1970, visits to medical practitioners for herpes have increased by more than 1000%. Herpes is particularly difficult for women, for whom the disease appears to contribute to a higher risk of cervical cancer. Herpes can be passed to a baby at birth. Approximately 1200 babies will be born with herpes infections this year. Half of them will die; of those who survive half will suffer permanent neurological damage. The STD program has completed a contract to design a pilot project on neonatal herpes. However, national implementation of this important surveillance network will be impossible under the President's budget. Surveillance of neonatal herpes infection is critical because no national surveillance of herpes in adults exists. In fact, allocations for herpes in the direct operations of the STD program in FY 1985 amounted to only half of the sum allocated in FY 1984.

Human Papilloma Virus Infections: The most common sexually transmitted disease caused by a virus is HPV, which causes genital warts, and is probably the most common of all sexually transmitted diseases. These infections are very difficult to treat and can be passed on to babies born of infected mothers, sometimes with life-threatening consequences. It is believed that there is a strong association between HPV infection and development of carcinoma of the cervix. So much remains to be learned about this highly contagious infection, yet there is virtually no program effort or education carried out by the STD program about this important disease, and the President's budget will prevent any such initiative.

Ectopic Pregnancy: Rising rates of sexually transmitted diseases have resulted in an epidemic of fetal dealth, which has gone largely ignored in this country. The number of ectopic pregnancies has quadrupled since 1970. Each of these pregnancies results in the death of the fetus and serious risk to the mother. Ruptured ectopic pregnancy has now become the leading cause of maternal death among black women in America. More than half of these pregnancies are directly attributable to pelvic infection caused by gonorrhea or chlamydia. Rates of gonorrhea are climbing, chlamydia remains uncontrolled, and the budget has decreased. The implications for ectopic pregnancy and fetal death over the next few years are staggering.

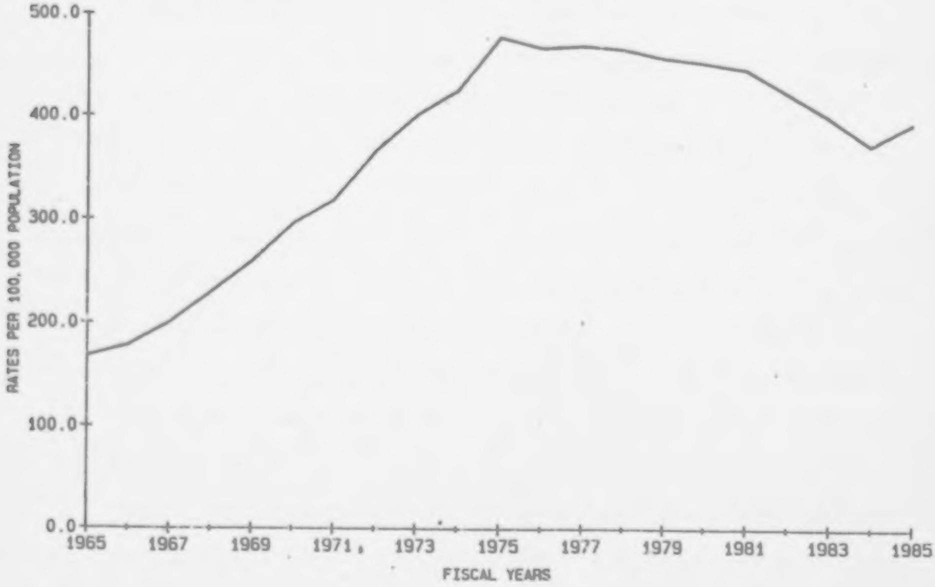
Infertility: A consequence of untreated sexually transmitted disease is involuntary infertility. This year between 110,000 and 150,000 women of child-bearing age will be rendered sterile as a result of these diseases, half of those women are under the age of 25. Sexually transmitted infections are the greatest single cause of unintended sterility in women of child-bearing age. The tragedy is that many of these cases of infertility could be prevented by control of chlamydia. But once the infection has damaged the fallopian tubes it is much harder to treat. The impact of the current budget will be ever-increasing rates of infertility.

Mr. Chairman, the number one public health emergency in this country is sexually transmitted diseases, including AIDS. The failure to recognize the critical importance of dealing with all of these diseases has resulted in disease rates unparalleled in human history. Some STDs may in fact be co-factors in the AIDS epidemic. To focus on one disease at the expense of other STD control has created a tragic situation. Since 1980, when AIDS was first recognized, more than 600,000 women have become sterile from venereal diseases. Since 1980 there have been more than 50 million new cases of sexually transmitted diseases. Since 1980 more than 6,000 babies have been born with herpes, half of them died. Since 1980, more than 400,000 ectopic pregnancies have occurred, at least half of which were caused by sexually transmitted diseases.

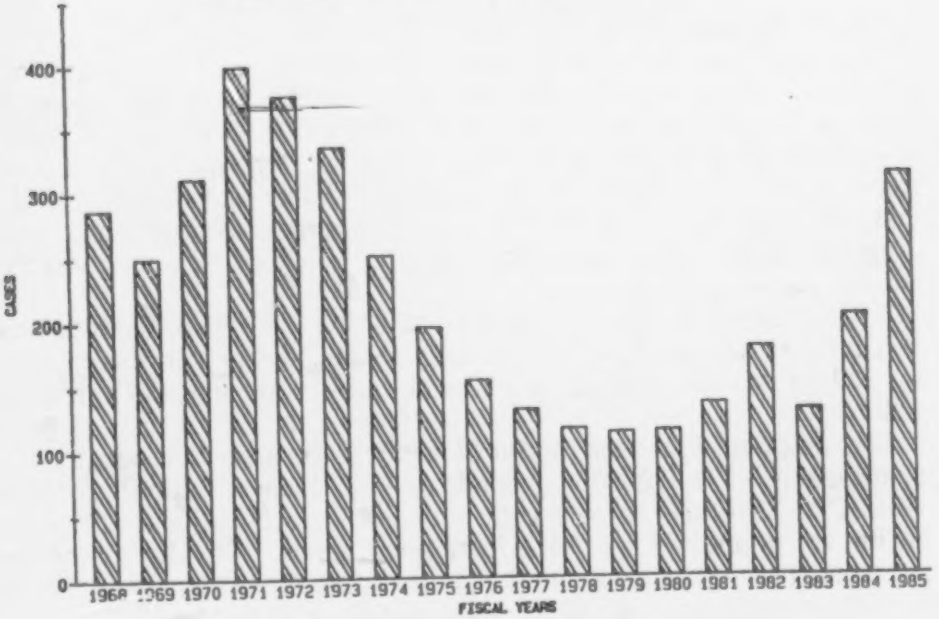
We urge the Committee to include strong report language which would prohibit the CDC from diverting funds from the STD program, or any other program, to other activities unless the terms of authorizing legislation are fulfilled. We urge the Committee to provide all necessary funding for AIDS efforts. Others who will testify before you will outline in detail the critical needs for this effort.

It is estimated that a national prevention and control program for chlamydia would require $50 million in additional funds to the STD program. The prevention and control of chlamydia, a disease affecting more than 3 million Americans each year, with devastating complications if undetected and untreated, must be a top priority for our nation. Chlamydia must become a reportable disease in every state, and each state must have the capability to prevent and control the disease. We urge you to provide this increase. Thank you, Mr. Chairman, for your leadership and for this opportunity to present our views.

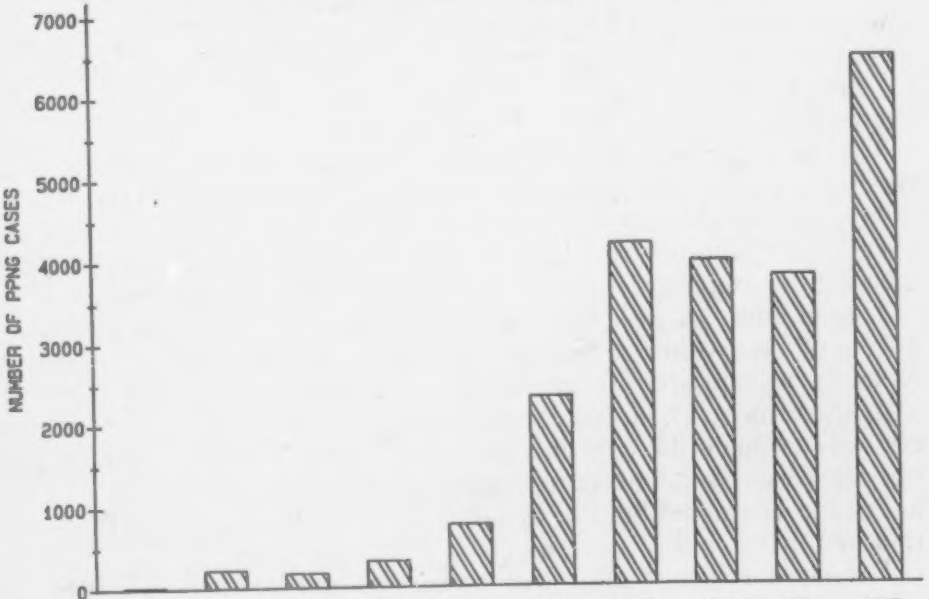
GONORRHEA CASE RATES PER 100,000 POPULATION
UNITED STATES, FISCAL YEARS 1965-1985



CONGENITAL SYPHILIS UNDER ONE YEAR OF AGE
UNITED STATES, FISCAL YEARS 1968-1985



PENICILLINASE-PRODUCING NEISSERIA GONORRHOEAE (PPNG)
NUMBER OF CASES
UNITED STATES (EXCLUDING OUTLYING AREAS): F.Y. 1976-1985



STATEMENT OF JEFFREY S. LEE, PH.D, PRESIDENT, ASSOCIATION OF UNIVERSITY PROGRAMS IN OCCUPATIONAL SAFETY AND HEALTH; DIRECTOR, ROCKY MOUNTAIN CENTER FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH, UNIVERSITY OF UTAH

Senator PROXMIRE. Mr. Lee?

Mr. LEE. I am here representing the Association of University Programs in Occupational Health and Safety and to urge you to restore funding for training to the National Institute on Occupational Safety and Health [NIOSH] budget within the CDC. Training is a mandated responsibility of NIOSH. The Occupational Safety and Health Act says that NIOSH shall "conduct directly or by grants or contracts education programs to provide an adequate supply of qualified personnel to carry out the purposes of the act."

NIOSH currently supports 14 comprehensive multidisciplinary education resource centers [ERC's] regionally located throughout the country, as well as several projects grantees to fulfill this mandated responsibility.

The program has been unquestionably a success, but equally unquestionably, it is critically dependent upon Federal support for survival. Over two-thirds of academic programs in occupational safety and health are supported by NIOSH training funds. Virtually all of the academic programs in occupational medicine, in occupational health nursing are affiliated with educational resource centers.

In addition to the traditional graduate training programs, over 17,000 professionals are trained annually in continuing education programs by ERC's. In my prepared statement, I present a graph showing the growth of training programs, the impact the reduction of funding has had, and the disastrous effect that complete elimination of the funding would have if Federal funding is not restored. The number of graduates would drop drastically and almost immediately to only 18 percent of the total graduated in 1981. Only an estimated one-fifth of the graduate degree programs would survive in the long run.

The need for occupational safety and health professionals is overwhelming and is increasing, not decreasing. Two recent Office of Technology Assessment reports "Preventing Injury and Illness in the Workplace" and "Reproductive Health Hazards in the Workplace," support the need for training of occupational safety and health profesionals.

The enormity of new hazards in the effects of hazardous wastes and effects of occupational chemical exposures on reproductive systems of females and men are just now being appreciated.

In these days, when our country faces a massive deficit, we must all critically evaluate the cost and benefit of federally supported programs, but the cost of training occupational safety and health professionals is minescule compared to the benefits. It is a long-term benefit that is returned many fold.

The latest statistics show that a work-related death occurs every 47 minutes, and a work-related injury occurs every 127 seconds. Annually, workers compensation payments exceed $16 billion per year, and th grossly underestimates the problems, since less than 5 percent of severely disabled workers receive compensation benefits.

The majority of occupational disease simply goes unrecognized and becomes a significant contributor to the Nation's health care costs and to the costs of our public supported medical care systems.

Consider that the NIOSH training budget is only five one-hundredths of 1 percent of the annual cost of workers compensation. If our graduates prevent only 1 percent of lung cancer deaths that occur annually, the savings would easily pay for the entire training program.

Finally, I would like to point out that with the funds, the effect NIOSH training has on academic programs is multiplicative. At Utah, for example, our continuing education program receives approximately $60,000 in NIOSH funding, which basically pays for the salaries of our C.E. staff. Yet our program has a budget of over $200,000. Without NIOSH funding to support salary, our program would disappear.

Researchers in other areas with NIOSH funding could indirectly foster development which could be effectively multiplied. Last year, the ERC directors, in collaboration with NIOSH and CDC, developed a new research initiative for ERC's which would capitalize on this potential.

This additional funding would allow the development of new research capabilities within ERC's to stimulate research funded through other sources and would further train students in research skills.

In summary, I would urge this committee to restore funding for NIOSH training. In 1976, Congress envisioned an ERC program of 20 centers costing $20 million. I am urging funding be restored at this year's level only, after Gramm-Rudman cuts, of $8.4 million, plus a minimum amount of $1.5 million to begin this research initiative, for a total request of $9.9 million.

Thank you, Senator.

Senator PROXMIRE. On page 3 of your written statement you made a startling statement. Your experience goes back 20 years or so, when you said that employers were asked whether they were aware of any health hazards in their plant, even if controlled. Three-fourths answered they did not feel a health hazard existed at that time. Trained surveyors then conducted an industrial hygiene survey of the plants, and only one-quarter of the plants did not have any employees at risk.

You say we have made progress since then, but we still have a very long way to go. There may be not quite that degree of ignorance, but there is a great deal of ignorance; is that correct?

Mr. LEE. Yes, sir.

Senator PROXMIRE. So there is probably a lot more exposure to occupational hazards than we might know about if we were vigorous in pursuing this program; is that right?

Mr. LEE. I think there is a great number of conscientious employers who are not knowingly exposing their employees to health and safety problems. That is probably one of the most distressing aspects of this problem.

Senator PROXMIRE. You say the Minerva project is designed to introduce occupational safety and health into graduate business schools. How commonly is that taught in advanced business schools?

Mr. LEE. It is probably taught only in 10 business schools and 10 schools of engineering across the country. We are just beginning to introduce those.

Senator PROXMIRE. Is it taught at some of the larger schools—Harvard, Stanford, and so forth?

Mr. LEE. Some of the big ones.

Senator PROXMIRE. I would be interested if you could submit for the record a list of the schools we are talking about.

Mr. LEE. I would be glad to do that.

Senator PROXMIRE. Perhaps we can do something about getting in touch with these people. I had one other question. The administration has tried to kill educational resource centers for years and has failed.

Mr. LEE. Yes, sir.

PREPARED STATEMENT

Senator PROXMIRE. I think they are funded at the current level under the Senate-reported budget resolution. From that standpoint, we are at least keeping the program where it is and not letting it die. I have tried to do better but that is difficult given our deficit situation.

Thank you very much.

Mr. LEE. Thank you, sir.

[The statement follows:]

STATEMENT OF JEFFREY S. LEE

My name is Jeffrey Lee and I am the current president of the Association of University Programs in Occupational Safety and Health and the director of the NIOSH Educational Resource Center located at the University of Utah.

I appreciate the opportunity to speak to this committee on behalf of the academic programs in occupational safety and health. In the past four years, my counterparts at the University of Cincinnati, the University of Michigan, the Johns Hopkins University, and the University of California at Berkeley have met with you for the same reasons I am with you today: to point out the critical importance of federal support for professional training in the field of occupational safety and health.

As you are aware, the Occupational Safety and Health Act of 1970 specifically mandated the then Secretary of Health, Education and Welfare, through the National Institute for Occupational Safety and Health (NIOSH), to "conduct, directly or by grants or contracts, educational programs to provide an adequate supply of qualified personnel to carry out the purposes of the Act" (Section 21(a)). In 1976, Congress authorized NIOSH to create 20 multidisciplinary Educational Resource Centers (ERCs), regionally located at major universities throughout the country. Funding for each of these centers was envisioned to be at least $1.0 million per year, and by 1980 the funding level of $12.9 million allowed funding of 12 centers. The academic community enthusiastically responded to this need, and by 1980 over 100 different academic degree programs were in place, offering degrees in Occupational Medicine, Industrial Hygiene, Occupational Health Nursing, and Occupational Safety. The number of graduates almost quadrupled from 1976 (176) to 1980 (747). Even more dramatic was the increase of continuing education programs offered by the institutions to practicing professionals to upgrade their skills. In 1976, approximately 1,600 individuals attended such courses; by 1980 this number had increased to almost 10,000 attendees.

In 1981, the funding level was drastically cut from $12.9 million to $8.7 million and further cut in 1982 to $5.8 million. In 1984 and 1985, despite the attempts of the Administration to eliminate these programs from the budget, funding was partially restored by Congress to $8.7 million. In 1986, funding was further reduced by the Gramm-Rudman-Hollings Bill to $8.4 million, and, as you all know, the 1987 Administration's budget once again completely eliminates funding for NIOSH training.

Approximately two-thirds of all the academic programs in occupational safety and health are supported through NIOSH training funding (1). Virtually all of the institutions offering residency programs in Occupational Medicine and all of the academic programs in Occupational Health Nursing are affiliated with ERCs (1).

A marginal decrease in funding has already had a significant effect on the training programs throughout the country. Last year, the University of Arizona was unable to maintain a full multidisciplinary program and lost their ERC funding, reducing the number of ERCs to 14. Although all of us have been moderately successful in obtaining partial state or institutional funding and have otherwise broadened our funding bases, we are still heavily dependent upon federal support. A survey of ERC directors indicates that, if federal support is not restored, the number of graduates will drop drastically almost immediately to only 18% of the total graduated in 1981, and only an estimated one-fifth of the graduate degree program would remain viable over the long run. Virtually all of the Occupational Medicine programs and graduate Occupational Health Nursing programs would disappear.

The need for occupational health and safety professionals is overwhelming. I remember when I first entered this field as a young engineer in 1967 with the U.S. Public Health Service, working for the organization that later became NIOSH. In 1968 we conducted a major survey of a representative number of companies to try to define the extent of occupational health problems nationally (2). One statistic has stayed with me all of these years. Employers were asked whether they were aware of any health hazards in their plant, even if controlled. Three-fourths answered that they did not feel a health hazard existed in their plant. Trained surveyors then conducted an industrial hygiene survey of the plants, and only one quarter of the plants did not have any employees at risk. I am confident that we have made significant progress in educating employers since this time, but we unquestionably have a long way to go. The NIOSH Minerva Project designed to introduce occupational safety and health into graduate business programs, utilizing ERCs in part, will help in this effort.

In Utah, a state not known for its heavy industry, every year I randomly pick a few small industries and offer them a free study as a training experience for my students. I continue to be amazed at the universal lack of awareness on the part of employers of the number and seriousness of health hazards that are present in their places of employment.

Consider further that much of the occupational disease that is occurring in this country goes unrecognized. It is not unusual to have an occupational disease not become apparent until decades after exposure. Since such diseases may have other causes besides occupational exposure, the association is not recognized by the employee, the employer, or even the employee's physician. Undoubtedly, these cases compose a significant percentage of those on the public-supported health care systems. They significantly contribute to the cost of health care in this country, which is currently over 10% of the gross national product--almost $300 billion--a cost often borne by the general taxpayer. As Senator Orrin Hatch stated at the Senate hearings investigating the suspected excessive cancer due to chemical exposures at Hill Air Force Base in Utah, "If there is a villain in this controversy, it is ignorance; ignorance of the proper methods relating to the protection of the employee from harmful chemical exposures; ignorance of the scientific knowledge related to the effects of the worker exposure to chemical substances; and ignorance of the now accepted fact that occupational causes of disease and illness often go undetected and unrecognized for a long period of time." I'm asking you today to help us reduce that ignorance.

The challenges facing professionals in the field of Occupational Safety and Health are increasing, not decreasing. We are only beginning to touch such critical areas as effects of chemical exposures on reproductive capability and neurobehavior and the occupational health risks of hazardous wastes.

Two recently released OTA reports support these conclusions. The OTA report "Preventing Illness and Injury in the Workplace" endorses the graduate training being provided by the ERCs and points out that cutbacks in federal training have reduced the number of trained professionals (3). The OTA report "Reproductive Health Hazards in the Workplace" states ". . . what is known about reproductive health hazards is far outweighed by what is unknown" (4).

Occupational disease and injury are preventable. A major element of the solution is to train professionals who can recognize, evaluate, and control occupational hazards and occupational disease. The beneficiaries are the general public, not only employers of these professionals.

Successes lie in the number of illnesses and injuries that are prevented; the number that occur are the failures. In 1983, the National Safety Council reported a work-related death occurs every 47 minutes and a work-related injury every 17 seconds, resulting in annual workers' compensation payments of $16 billion (5), and this underestimates the problem. A survey done by the Department of Labor revealed that only 5% of workers who are severely disabled from an occupational disease receive worker compensation benefits (6). If partially disabled workers were included, the percentage would probably fall to about 2%. Consider that the total 1986 NIOSH training budget is only five one-hundredths of a percent of the annual cost of workers' compensation. Last year, my colleague from the University of California at Berkeley, Dr. Robert Spear, pointed out to this committee as an example: if one of our graduates in safety and ergonomics were to prevent just two back injuries from occurring (costing an average of $6,000/case in compensation alone), he would have paid for his education. There are approximately 150,000 cases of lung cancer occurring annually in the U.S.; probably 5-10% of these are caused by occupational exposures. If we were successful in preventing only 1% (or 1,500) of these lung cancer cases per year, the savings in health care costs alone would easily pay for the entire NIOSH training program.

Graduate training does not exist in a vacuum in a university setting. It feeds on and indirectly supports research and community service. Last year, the ERCs, in collaboration with NIOSH and CDC, defined a new research initiative whereby the mandated training function of the ERCs would be expanded to foster the development and expansion of occupational health research and the development of research skills in our students. Currently, 45% of NIOSH research grants are lodged in ERC institutions. The cross-fertilization of research and training is apparent and has great potential. The House Appropriations Committee has likewise noted the importance of this research effort within ERCs. Last year's House report language on occupational safety and health (pp. 32-33 of HR 99-289) states as follows:

> The Committee recognizes the important inter-relationship between successful training and innovative research programs in an academic setting. Graduates of more intensive research-based training programs will help provide new, imaginative, and cost-effective solutions to occupational safety and health problems in the United States. Such an expansion of the mission of ERCs to include research and research training to accompany ongoing practitioner training would be an important initiative in strengthening these graduate educational programs. It would also stimulate ERC training and research efforts in programs designed to safeguard worker and community health in the cleanup of hazardous waste sites and in other high-risk occupational settings.

Although NIOSH and CDC supported this initiative, higher levels within the Administration rejected the plan and again recommended total elimination of the ERC program.

We recognize that we all must do more with less when our country is facing a massive deficit. In 1976, Congress envisioned an ERC program with 20 centers and a $20 million annual budget. We are now, 10 years later, requesting only the current funding level after Gramm-Rudman cuts of $8.4 million, plus a minimal amount of $1.5 million to begin the research initiative, strongly supported by the House Appropriations Committee in its last year's report. I, thus, respectfully urge you to support the restoration of a total $9.9 million to the NIOSH training programs budget.

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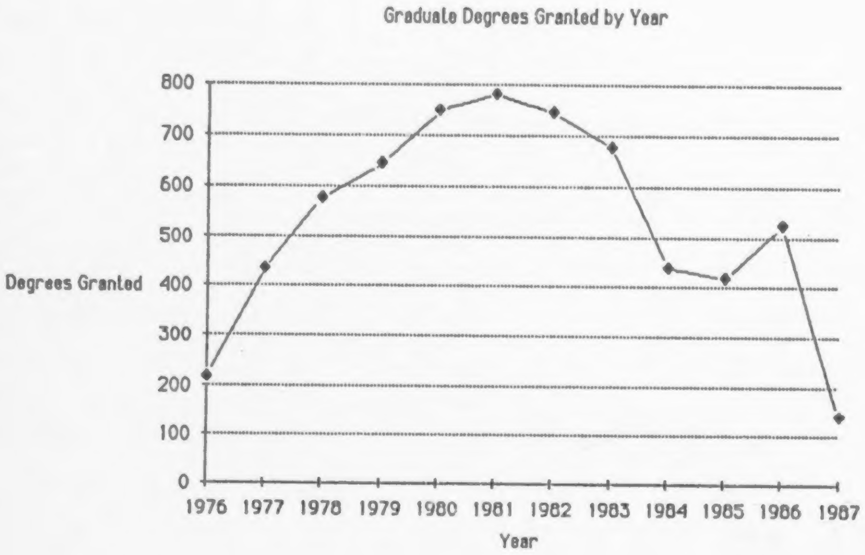
2. Bureau of Occupational Safety and Health, USDHEW: Occupational Health Survey of the Chicago Metropolitan Area, 1969.

3. U.S. Congress, Office of Technology Assessment. Preventing Illness and Injury in the Workplace. OTA-H-256, Washington, D.C., April 1985.

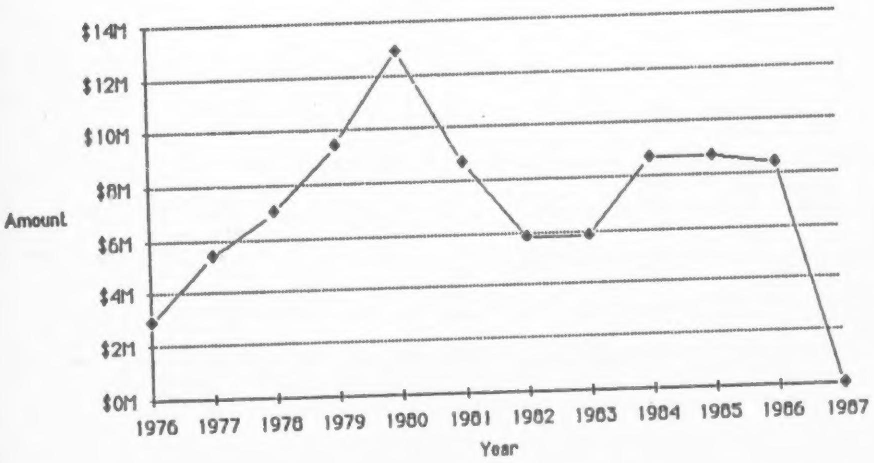
4. U.S. Congress, Office of Technological Assessment: Reproductive Health Hazards in the Workplace. OTA-BA-266, Washington, D.C., December 1985, p. 3.

5. National Safety Council: Accident Facts, 1984.

6. An Interim Report to Congress on Occupational Diseases. Report No. 0-311-416/4007. Washington, D.C.: U.S. Government Printing Office, 1980.

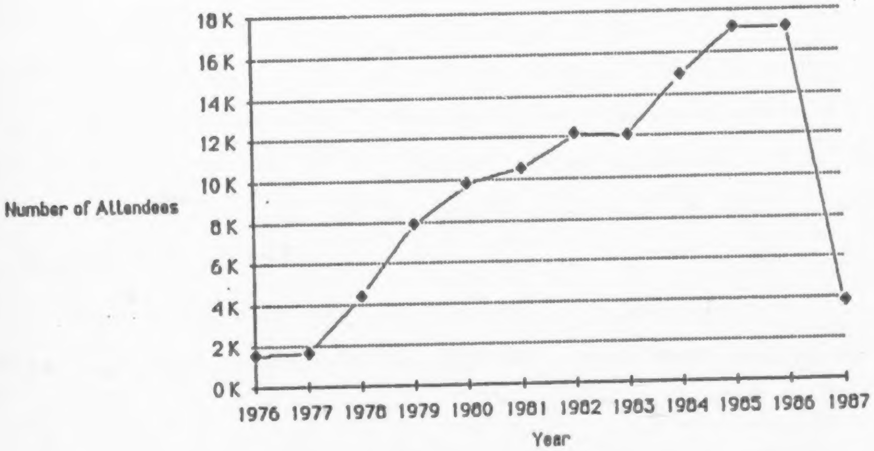

Graduate Degrees Granted by Year

Training Funds by Year
(Millions of Dollars)



EFFECT OF FUNDING CHANGES ON NUMBER OF GRADUATES FROM BOTH ERC AND SINGLE-DISCIPLINE PROJECT GRANTS

Attendees in Continuing Education Courses by Year
(Thousands)



SUPPLEMENTAL STATEMENT

Senator Proxmire requested further information concerning Project Minerva, the NIOSH educational program designed to educate students in schools of business in matters of occupational safety and health. The following sixteen universities were each awarded approximately $10,000 to participate in the initial pilot Minerva study to incorporate resource material into curricula for schools of business: Eastern Illinois University, Georgia State University, Harvard University, Miami University of Ohio, University of North Carolina, University of Kansas, The Johns Hopkins University, University of Hawaii, North Texas State University, University of Oregon, University of Utah, University of Washington, Xavier University, University of South Florida, University of Southern Mississippi, and Virginia Tech. The above universities include five of the NIOSH Educational Resource Centers (ERCs).

Project Minerva was begun with only a minimal expenditure. In addition to the above schools, several additional schools have not received funding but have been introduced to the occupational safety and health concepts of the project.

The initial phase of Project Minerva is to simply alert schools of business to the need for students to receive information and instruction in occupational safety and health. The second phase includes efforts to energize and facilitate these schools in providing the necessary information and instruction concerning safety and health issues. The third and final stage of the project is to provide participating schools with instructional materials and other resources suitable for incorporation into existing curricula or for development of new courses.

Additional funding for this worthwhile project is definitely warranted. The goal should be to achieve one of the objectives set by the U.S. Department of Health and Human Services for the nation in occupational safety and health, which states, "By 1990, all managers of industrial firms should be fully informed about the importance of, and methods for, controlling human exposure to the important toxic agents in their work environments."

HEALTH AND SAFETY IN THE WORKPLACE: A NEW CHALLENGE FOR BUSINESS SCHOOLS

The story of Project Minerva

David S. Thelen, Donna E. Ledgerwood and Charles F. Walters

Is it possible for a large corporation with assets totaling $2.2 billion, net worth of $1.2 billion, a very healthy cash flow position and an annual income potential of $150 million to file for bankruptcy under Chapter 11? Yes, and this type of action is occurring with increasing frequency due to a very important problem: Safety and health in the workplace.

The safety and health problem has been reduced continually since 1936, a year in which 35,000 deaths were reported. Most professionals agree that with current technology we can and must continue to reduce occupational safety and health problems. In 1970, at the time the Occupational Safety and Health Act was being formulated, an estimated 14,200 American workers died on the job, 2.2 million suffered disabilities, and another 300,000 to 500,000 suffered from occupationally induced illnesses.

Considerable progress has been made in reducing death, injury and illness at the worksite since the passage of the Occupational Safety and Health Act of 1970, but the progress has been painfully slow and the cost of accidents remains staggering. National Safety Council data for calendar year 1983, 12 years after the enactment of the Act, showed 11,200 work-related accidental deaths, approximately 1.9 million disabling work-related injuries and a total work accident cost of at least $32.1 billion.[1]

In addition to the often intense personal suffering and financial loss to the injured worker and family, worker injuries add greatly to worker's compensation costs. Employee injuries on or off the job disrupt productivity, increase downtime, disrupt production schedules and add to hiring, scheduling and training costs. Further, the bad press which frequently follows a major accident (and sometimes even a minor one) can seriously impair the image of a firm in the community and on the open market. Today, management is open to scrutiny not only from superiors but also from the work force, competitors, governmental agencies, the public, special interest groups and the media. Literally, there is no place to hide when it comes to employee health-related issues.

Since 1971, the National Institute for Occupational Safety and Health has invested approximately $70 million through its training grant program to help ensure an adequate supply of safety and health professionals needed to protect the American worker. NIOSH has expanded its manpower development activities to extend beyond the traditional training of engineers, physicians, nurses and other occupational safety and health professionals to include education for future managers in specialized areas of occupational safety and health.

Managers who make major resource allocation decisions need to be knowledgeable in areas of safety and health. Many technical safety and health professionals say that safety and health is frequently a "hard sell" item to upper management, despite the fact that such training invariably pays high dividends to the safety-minded manager. One reason for ignoring health and safety-related issues is the American manager's emphasis on short-term profits and the "bottom line." A second reason is the lack of academic exposure to health and safety issues. This lack of preparation often leads to poor decision-making regarding health, safety and security issues. These types of decisions can ultimately result in loss of advantage in a competitive market, litigation and possible bankruptcy.

Some of the nation's largest corporations have achieved outstanding occupational safety and health records by, among other things, involving all levels of management in their safety and health training programs. The commitment to safety and health must begin at the top of the corporate ladder and pervade the entire organizational hierarchy. Performance appraisals and promotions should incorporate safety and health experience directly into those decisions affecting all managerial and nonmanagerial employees. As noted by Lester A. Hudson, CEO for Dan River, Inc., "Management must be committed absolutely and positively! Safety and health must come from the very top of the organization. The commitment must be sincere, genuine and serious...It must be given equal billing with other manufacturing (line) objectives, such as quality and efficiency, and labor turnover. Safety effectiveness must become part of the criteria by which we measure supervision."[2]

Another safety and health advocate, Bruce W. Karrh, MD, vice president for safety and environmental affairs for E.I. duPont de Nemours and Co. (an acknowledged industrial leader in corporate safety and health programs) has said that the duPont reputation was earned because of a "commitment to safety and health from top management on down through the organization structure..."[3] Russell DeReamer, former corporate safety manager for IBM, adds: "There should be no argument that the same management principles and concepts that are applied to quality, cost, and production, must also be applied to safety."[4]

In a recent article in *Business Horizons*, Professor Herbert G. Hunt III, assistant professor of accounting at Pennsylvania State University, listed seven tangible and six intangible benefits of a well-managed safety and health program.[5] The following benefits were detailed in Hunt's classifications:

Tangible benefits of a well-managed OS&H program

- Reduction in casualty and worker's compensation premiums
- Increased worker productivity (efficiency)
- Improved absenteeism rate
- Reduction in the number of employee problems
- Decreased labor turnover
- Future savings of attorney's fees related to employee/employer litigation
- Avoidance of the following indirect costs: (1) wages paid for lost time; (2) cost of training new workers; (3) uninsured medical costs; and (4) overtime necessitated by unproductive workers due to health problems.

Intangible benefits of a well-managed OS&H program

- Improved corporate image
- Increased market value of stock[6]
- Improvement of employee morale, job satisfaction and job attitude[7]
- Increased attractiveness of the company to prospective employees
- Reduced pain and suffering by employees and their families
- Improved relations with governmental agencies.

Hunt insists that we consider the intangibles as absolutely essential for a balanced evaluation of the nonroutine type of decision usually required in health and safety. He concludes: "The nonquantifiable social, political and human factors in a given situation may easily be the most important elements in the analysis, and ones which, unfortunately, were often ignored in years past."

As with any program, the safety and health function of any company or corporation must be managed effectively and efficiently. One of the reasons why many of this nation's business establishments have not been more successful in reducing injury and illness-producing incidents may be found in the lack of application of management principles and concepts to the safety and health function within the organization. The reasons for this may be traced both to management and to the occupational safety and health specialist. Whether they relate to marketing, operations, personnel, finance, accounting, information systems or safety and health, the problems of business will respond to the timely and intelligent application of the principles of sound management. However, frequently this is not done.

In 1979 NIOSH reported the findings from its study of safety practices observed in five industrial plants that had excellent safety records. From this study, NIOSH identified specific factors which distinguished successful safety program practices.[8] Three of these factors were:

- Managerial commitment to safety
- Managerial efficiency with respect to safety
- Education and training of *all* employees, not just those in high-risk jobs.

Considerable progress has been made in reducing death, injury and illness at the worksite since the passage of the Occupational Safety and Health Act of 1970, but the progress has been painfully slow and the cost of accidents remains staggering.

"Management efficiency" was defined as "the anticipation of potential safety problems, adequate planning to overcome these problems and evaluation of the efficiency of management and employees toward overcoming the identified problems." The results of this study indicated that the identification, elimination and control of safety risks are activities that call not only for expertise and deployment of specialist skills and services, but that they also are essential parts of every manager's job—from the first-line supervisor through upper management to the CEO. Such safety and health skill and knowledge is not intuitive, however. The development of both knowledge and skills must be taught not only to existing managers but to aspiring future managers—who presently are business majors in our nation's colleges of business.

What is Project Minerva?

The seeds leading to the inception of Project Minerva were planted about 10 years ago, when NIOSH received a call from a professor at a prestigious business school who asked for occupational safety and health training material suitable for use in the classroom. When asked why this material was needed, the professor replied, "Upon graduation, our MBA graduates are being interviewed for jobs, and during the course of the interview, they are asked: '...in the event you are hired, you will be responsible for worker safety and health. Do you feel qualified to carry out these responsibilities?' Most of these graduates then reply: 'What's that?' "

NIOSH thought that an accredited college of business should include in its core body of knowledge some exposure to issues related to employee safety and health.

The strategy of Project Minerva is consistent with the U.S. Department of Health and Human Services' objectives for the nation in occupational safety and health, one of which states: "By 1990, all managers of industrial firms should be fully informed about the importance of, and methods for, controlling human exposure to the important toxic agents in their work environments." Project Minerva is designed to encourage this nation's schools of business to integrate the management of safety and health principles and concepts into their existing curricula. Sixteen schools of business have been targeted by NIOSH for special assistance. By the turn of the century, it is hoped that all accredited colleges of business will graduate bachelor and master degree students who have been trained to appreciate the impact of safety and health on all phases of their business curricula.

How is NIOSH implementing Project Minerva?

NIOSH is implementing Project Minerva through a three-phase effort. The initial phase is to alert schools of business to the need for students to receive information and instruction in occupational safety and health. The second phase includes NIOSH efforts to energize and facilitate these schools to provide the necessary information and instruction concerning safety and health issues. The third and final stage of Project Minerva is to provide participating schools with instructional materials and other resources suitable for incorporation into existing curricula or for development of new courses.

The first phase, alerting schools of business to the need for students to receive information and instruction in occupational safety and health, is a challenging task in itself. Presently, input is being obtained from business, industry, government and academia to determine an optimal strategy for implementation. Numerous planning sessions have been held with representatives from these groups, and plans have been formulated for a methodology to contact potential business schools. Efforts to date have ranged from workshops for business school faculty to broad promotional efforts. These efforts have resulted in hundreds of requests for information and endorsements of the project, which have come not only from schools of business but from industry as well. NIOSH has worked closely with the Academy of Management, the National Safety Council, the National Safety Management Society, the Occupational Safety and Health Administration and representatives from the American Assembly of Collegiate Schools of Business.

Literally, there is no place to hide when it comes to employee health-related problems.

Phase Two, energizing schools of business to provide information and instruction on occupational safety and health, is being done through personal contacts with selected schools of business. Sixteen schools presently participating in a pilot study to incorporate resource material into their curricula include:

- Eastern Illinois University
- Georgia State University
- Harvard University
- Miami University of Ohio
- University of North Carolina
- University of Kansas
- Johns Hopkins University
- University of Hawaii
- North Texas State University
- University of Oregon
- University of Utah
- University of Washington
- Xavier University
- University of South Florida
- University of Southern Mississippi
- Virginia Tech.

The concept of Project Minerva has been well received in every business school visited to date. However, NIOSH has discovered that although the business schools are enthusiastic about the integration of occupational safety and health content, they lack the time and expertise to develop the necessary course materials. Phase Three of Project Minerva can help in this regard.

Phase Three provides participating schools with safety and health resource materials suitable for inclusion into their curricula. The instructional material includes a series of case studies designed to illustrate current safety and health management issues in a classroom setting, as well as lecture modules that can be integrated into courses that are already being taught such as business policy, business law, marketing management, organizational behavior, finance, etc. The latest resources being developed by NIOSH include a book of readings and an annotated bibliography.

Schools of business that have an interest in including all or part of the material into their curricula should contact:

The National Institute for Occupational
Safety and Health
Division of Training and
Manpower Development
4676 Columbia Parkway
Cincinnati, OH 45226.

A future project planned by NIOSH is a publication that will list suggested occupational safety and health problems suitable for theses and dissertations by graduate students in schools of business. NIOSH also plans to encourge and jointly sponsor a series of workshops throughout the country to which business school faculty and doctoral students will be invited to discuss current and future objectives and goals of Project Minerva. Participants will also receive instruction in how to use the instructional materials.

Many technical safety and health professionals say that safety and health is frequently a "hard sell" to upper management, despite the fact that such training invariably pays high dividends to the safety-minded manager.

Finally, NIOSH is encouraging selected industries to make internships available for faculty of schools of business, so that they may learn firsthand how the occupational safety and health effort is managed in America's top industries and in their respective cities. It is hoped that these professors will then share their knowledge with peers and students after returning to their respective universities.

Why is there so much interest in Project Minerva?

A major reason why NIOSH is vigorously supporting Project Minerva is related to the results of a study conducted by the National Safety Management Society, which confirmed an earlier hypothesis by the agency that "college educated" managers have received little or no information—much less classroom instruction—on occupational safety and health during their formal academic training. The 1984-1985 academic year thus was targeted as the time to act forcefully to correct this situation.

The second reason Project Minerva is gaining academic support is due to revised assumptions upon which both the theory and practice of management are based. In his book *Technology, Management and Society*, Peter Drucker states, "Because our society is rapidly becoming a society of organizations, all institutions, including business, will have to hold themselves accountable for the 'quality of life'...In the business enterprise, this means that the attainment of the 'quality of of life' increasingly will have to be considered a business opportunity and will have to be converted by management into profitable business."[9] The values of the worker are changing. The workplace is changing. Thus, managers must be attuned to these changes and take them into account during their planning, organizing, directing, staffing and controlling functions. A safe and healthful environment is one of the key ingredients in any effort to improve the quality of life, both in the workplace and at home.

The third catalyst stimulating business schools' interest in Project Minerva is the burgeoning criticism of higher education by the business community and by society at large. More specifically, the curricula of this nation's schools of business, including the curricula of the more prestigious schools, have become too quantitative and too theoretical. Courses often lack the applied orientations that is necessary for managers to make better decisions.[10,11]

A fourth reason for business schools' interest in Project Minerva is the need to share with current and future managers information that correlates the financial status of corporations with well-structured and efficiently managed occupational safety and health programs. DuPont and Procter and Gamble are examples that epitomize how, through safety efforts, corporations can reap enormous savings. In its U.S. plants in 1980, duPont had an annual rate of 0.12 accidents per 100 workers, or one-twenty-third the National Safety Council's average rate for all manufacturers for that year. Had duPont's record been average, the company would have spent more than $26 million on additional compensation and other costs, or 3.6 percent of its profits. To make up the difference, in view of the company's 5.5 percent net return on sales at the time, duPont would have had to increase sales by nearly $500 million. This is just one example of the huge savings that can be realized when a company manages the occupational safety and health function in the same way it manages other business functions.

A fifth reason why business schools have expressed interest in Project Minerva is that emphasis on occupational safety and health is shifting dramatically from the "careless worker" to the "careless employer". As in equal employment opportunity regulations, employers must be aware that they are bound by the principle of administrative law. Contrary to civil law, administrative law places the burden on the employer, who is guilty until proven innocent.

The commitment to safety and health must begin at the top of the corporate ladder and pervade the entire organizational hierarchy.

Legislation, litigation and arbitration actions have now established sufficient evidence to swing the accident-prevention offensive away from the worker to the employer. Management can no longer operate under the mistaken belief that workers are at fault in any specific percentage of the injuries and illnesses incurred in industry. Any one statistic at any one company may not hold true for other situations. In addition, social responsibility and community pressures are causing management to look for more rational explanations to account for losses within the organization. The focus of management is thus changing from looking at the effects of certain practices (such as how many accidents per plant location) to the prevention of accidents by identifying the potential sources of such accidents.

W. Edward Deming, an internationally known consultant in statistical methods whose work in Japan helped to create a revolution in quality and economical production, has often stated that poor quality is 85 percent a management problem and 15 percent a worker problem.[12] Much the same could be said for occupational and environmental problems in American industry.

It is believed that Project Minerva will continue to be well-received. Therefore, NIOSH is planning to stimulate research articles and presentations among such professional organizations as the Academy of Management and the American Society for Personnel Administration. The agency believes that Project Minerva can help to significantly strengthen current business school curricula by providing occupational safety and health educational resources for training today's and tomorrow's managers.

DuPont and Procter and Gamble are examples that epitomize how, through safety efforts, corporations can reap enormous savings.

President Reagan has called for a public-private partnership to enhance the aims of business and to meet social goals at the same time. Protecting the American worker, our most important national resource, offers business management and our educational institutions their greatest challenges of this century. NIOSH has invested over $200,000 in personnel, time and funds in Project Minerva to date. In addition, The Minerva Education Institute, a not-for-profit corporation, has been created to assist and augment the NIOSH initiative. In a true sense of cooperation, industry's support of The Minerva Education Institute will be a much needed response to the President's call for a public-private parnership. For more information, please write to The Minerva Education Institute, Drawer 246, Carrboro, NC 27510.

Conclusion

An appropriate note for this article comes from John V. Grimaldi, executive director of the Institute of Safety and Systems Management at the University of Southern California: "The common sense that underlies Project Minerva deserves the advocacy of every reasonable person."

Project Minerva challenges our nation's business schools to help prepare future managers for the awesome task of protecting our most valuable resource, the American worker, through the promotion of occupational safety and health management concepts and principles in our nation's business schools. Your involvement and creativity can make a difference. The lives you save may be more than merely a matter of academic interest. ☐

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STATEMENT OF HARRY TETER, DIRECTOR, ATLANTIC EMERGENCY MEDICAL SERVICES COUNCIL

ACCOMPANIED BY SUSAN McHENRY, STATE EMERGENCY MEDICAL SERVICES DIRECTOR

Senator PROXMIRE. Our next witness is Dr. R. Adams Cowley, director of the National Study Center for Trauma and Emergency Medical Services [EMS].

Mr. TETER. Mr. Chairman.

Senator PROXMIRE. Dr. Cowley.

Mr. TETER. I am Harry Teter'

Senator PROXMIRE. I beg your pardon.

Mr. TETER. Dr. Cowley has been detained at the Baltimore Shock Trauma Center in Baltimore. He has authorized Susan McHenry, the State emergency medical services director, and myself, to make a few comments. He, of course, has a comment in the record.

Senator PROXMIRE. Let me just tell you that I think very highly of your trauma center.

Mr. TETER. Thank you.

Senator PROXMIRE. I will tell you why. About 10 years ago, my oldest son was driving back home. He took the beltway around Baltimore. His car stopped, a brand new car. He went around to look under the hood. A car smacked into him and knocked him 150 feet across the pavement. He smashed his head and was in bad shape. A helicopter landed and took him to the trauma center. Since then, he has been 100 percent better than before he was hit. It knocked some sense into him. [Laughter.]

Mr. TETER. Senator, on behalf of Dr. Cowley, I am sure he takes total and complete credit for that. I would like to say for Dr. Cowley, you know he has been a pioneer in the emergency medical services field. He advocated the development of EMS systems many, many years ago to save lives, and through the use of helicopters, through use of rapid transportation to trauma centers, or to properly designated centers, we are saving lives.

He regrets very much that, in recent years, when the program of EMS was a categorical program, it has been folded into the block grant, that the Federal emphasis and push that was needed for these systems has evaporated, and there are certain facts that I would like to ask Ms. McHenry to also give, and then I will go to mine.

Senator PROXMIRE. Go right ahead.

Ms. MCHENRY. I currently serve as the director of emergency medical services for the Commonwealth of Virginia and represent not only Dr. Cowley's thinking on this, but that of our colleagues across the country who direct their various State programs. We have the responsibility for trying to develop comprehensive emergency medical care systems within our respective States, and also for licensing ambulance services, providing training for the attendants for those services, and really trying to maintain a quality service that can provide for our citizens.

We have enjoyed a great deal of support from the Federal Government in the past, particularly through the Emergency Medical Services System Act, that provided us with a substantial amount of financial support as well as national leadership, really, in the years of 1973 through 1981, when we then switched over to the preventive health and health services block grant.

Since the transition to the block grant, we have seen a decrease in the amount of support, not only financial, but certainly in the leadership arena. The Department of Health and Human Services has essentially not only reduced its role, but eliminated its role in providing guidance and leadership for the continuing improvement of emergency medical care.

I think we have seen a little bit of a change in that, very, very recently, as the CDC has established its Center for Injury Control, and it is beginning, I think, to become a little bit more involved in this and will be anxious to work with us. We would encourage that that effort be continued and be strengthened, because there is so much that can be gained with that in terms of reducing death and disability across the country.

In regard to the preventive health and health services block grant, we have done a recent survey of our counterparts across the country. We are finding that less than $15 million of that block grant is going to emergency medical services. That represents approximately 16 percent of the total block grant initiative.

I think one thing that we have seen happen in the 5-year history of that block grant is that there has been a tendency to emphasize and to put priority on the preventive health issues, and even drop out of the title that is supposed to be preventive health and health services those health services aspects, those treatment aspects.

Those of us in the EMS community are very committed to preventive efforts and have, I think, played a very active role across the country in supporting prevention measures such as safety belts and other things that can help us to prevent injuries.

But we all must recognize that we can't prevent all those injuries from taking place. We may reduce the severity of the injuries in many cases, and we may reduce the numbers, but we will never stop them. When those fail, when those preventive efforts fail, the health services or the treatment aspect has got to be in place if we are going to save lives and if we are going to reduce injury, and that is absolutely essential.

Emergency medical services is a program that is of potential benefit to every single person in this country. It doesn't have a special interest group, because everybody has the potential of suffering from a sudden illness or a serious injury. We would urge your continued support of that preventive health and health services block grant, but particularly, your attention to making sure that the health services aspects are looked at with the same emphasis as the preventive health aspects and would really urge flexibility in the expenditure of those funds so that we might meet our varying needs across the country for emergency medical care.

Senator PROXMIRE. Thank you very much.

Mr. TETER. Senator, I am Harry Teter. I am director of the Atlantic Emergency Services Council and work with several emergency organizations in EMS.

As you know, this is a major problem in this country. The provision of EMS is not uniform throughout this country. In certain areas, one is better off by a long shot because there is good transportation; there is good care at the scene of the accident and there is good care at the hospital. In certain areas, that does not exist, and that should not be. We should have systems networked throughout this country.

As Ms. McHenry has just said, every one of us could be a potential victim of trauma. It doesn't matter where we are. It can happen and happen suddenly. If there is not a system there, our life may be lost or we may have injuries that we suffer through our entire life. If there is a system there, as, indeed, in some of the States, such as Maryland, we have proved that we can reduce death and disability dramatically. We have people returning to productive lives.

Last year, there were over 100,000 people that were killed and over 2 million people suffered injuries that were needing of an emergency medical services system. It was a $90 billion problem.

Senator PROXMIRE. How big a problem, again?

Mr. TETER. $90 billion.

Senator PROXMIRE. $90 billion?

Mr. TETER. $90 billion. We include with that the direct costs and the indirect costs; the loss of work; the loss of life; then the rehabilitative services that are needed and, of course, the direct medical.

Senator PROXMIRE. It doesn't include lawyers' fees. [Laughter.]

Mr. TETER. No, sir; if that were true, I am sure it would go up much more. I would also like to draw your attention to this book entitled "Injury in America." I would be delighted to provide you a copy of it if you have not seen it. It was recently done at the direction of one of your colleagues, Congressman William Lehman, who is very interested in this from the prehospital stage.

It was published just recently and states again that trauma is one of the leading health problems we have in this country. It is the greatest killers of children, young people, I should say, those from 1 to 40 years old, and the third greatest overall killer.

We can only attack it if we have attention given by the Federal as well as the State and local governments at the source of needed resources. We ask for the full appropriation for this program, and CDC will certainly echo what Ms. McHenry said as far as attention to be given to EMS.

Senator PROXMIRE. You say you are requesting the full appropriation. How much is that?

Mr. TETER. I believe it is $89 million that goes to CDC this year.

PREPARED STATEMENTS

Senator PROXMIRE. That is right, $89.5 million. Thank you very much. Both of you gave helpful and impressive testimony. Your statements will be included in the record at this point along with other statements submitted for the record on appropriations for the Centers for Disease Control.

Mr. TETER. And we thank you, sir.

[The statements follow:]

STATEMENT OF R. ADAMS COWLEY

Mr. Chairman, I am R Adams Cowley, M.D., Director of the Maryland Institute for Emergency Medical Services Systems and the Director of the National Study Center for Trauma and EMS. The Maryland Institute for EMS is a leading developer of EMS and is the home of one of the nation's largest shocktrauma centers. I appreciate the opportunity to testify today on behalf of full funding for the Preventive Health Care Block Grant.

IN the years betwen 1973 and 1981 the Federal government had a categorical program for EMS which helped to develop EMS systems throughout this country. The challenge was great and during the life of that program great strides were made to achieve the goal of a nationwide network of systems. Had this been achieved a person injured in this country would receive state-of-the-art care no matter where he was injured. Unfortunately that categorical program ended before the job was complete. The job is now left to the states with the assistance of funds from the Department of Transportation and to a much lesser extent from Health Human Services through the Preventive Health Care Block Grant.

Although the situation is somewhat better than at the initial implementation of the block grant, EMS is still not faring particularly well competing for the Preventive Health Care Block Grant funds. Many of those dollars now go into prevention programs and although these programs are laudatory, EMS and the health services programs present equally critical needs that must be addressed. I would hope that this subcommittee would specifically direct that more attention and more dollars be directed to health services and specifically emergency medical services.

I am happy to see the publication of a new study titled Injury in America. It recognizes that trauma is still a major disease in this country that needs to be addressed. The irony is that we know what works in dealing with trauma, namely prompt, definitive treatment as provided by a comprehensive resource-coordinated system. We know how to build and maintain EMS systems. We don't need to discover a mystery cure, we need only apply what we already know. We have proved that the systems work. I have proved that in Maryland. But these systems cost money - money that must come from Federal, state and local sources. All must commit to this in order to solve this critical problem. Until we do this, too many of our citizens will die nedlessly or will suffer life long disabilities. With adequate funding systems can be built and maintained, people who are victims of trauma will live and be able to return to productive lives. Surely this is a superior investment of dollars and I urge you to make that investment.

STATEMENT OF HARRY TETER, JR., DIRECTOR, ATLANTIC EMERGENCY MEDICAL SERVICES COUNCIL

Mr. Chairman, on behalf of the Atlantic Emergency Medical Services Council I appreciate the opportunity to appear before you today to testify in support of full appropriations for the Preventive Health Services Block Grant. The Atlantic EMS Council is composed of emergency medical services representatives from the states of New Jersey, Pennsylvania, Delaware, Maryland, the District of Columbia, Virginia and West Virginia. This region contains some of the finest, most advanced emergency medical services systems in the United States. Federal, as well as state and local dollars have been critical to the development of these systems which have now saved countless lives.

Since categorical funding was eliminated five years ago emergency medical services has not uniformly fared as well competing for block grant funds at the state level. For example, in FY 1983 all but one state reported cuts in EMS funding. Those cuts ranged from 7%-84% according to the Center for Disease Control which administers the block grant. The Government Accounting Office, in reviewing state implemention of the block grant reported that a number of states had discontinued funding for EMS "because state officials believed it to be a local responsibility." Since then emergency medical services has fared better as indicated by figures from the National Association of State Emergency Medical Services Directors but more is still needed. We know that the development and maintenance of EMS systems is critical to saving lives and this requires funds from all levels of government. The Preventive Health Care Block Grant dollars play a vital role.

Increased dollars for EMS is justified in light of the program's effectiveness and the magnitude of the problem. Trauma is the greatest killer of our young, those from ages 1-40 years old, and the third overall greatest killer. EMS is primarily concerned with the critically ill and injured victims of trauma. Time is critical and a victim treated by an EMS team will receive initial care and be in a definitive medical center within 60 minutes. If comprehensive EMS services are available many who would otherwise die are saved.

Unfortunately, Mr. Chairman, this success is applicable only to those areas that have the benefit of EMS availability. Creation of new facilities, expansion of existing services, and establishment of linkages within the EMS network are necessary for optimal implementation. Systems must cover broad areas rather than small localities because victims may require the services of a variety of specialized facilities such as a shocktrauma center, a burn unit, or a pediatric emergency facility. Traditional geographicl and political boundaries are irrelevant in most cases. Provision of emergency medical services is not solely a local issue. The Federal role is particularly significant because the most effective system requires interstate networking with a coordinated national focus. The Federal commitment to supporting EMs must be made if we are to realize its full potential.

Accordingly, we recommend targeting funding for EMS. Those monies are essential if new state-of-the-art services are to be established nationwide.

Thank you for this opportunity to commend and I will be happy to answer any questions.

STATEMENT OF THE NATIONAL ASSOCIATION OF STATE EMERGENCY MEDICAL SERVICES DIRECTORS

Mr. Chairman and members of the Subcommittee, my name is Susan D. McHenry and I am here today representing the National Association of State Emergency Medical Services Directors. My other role is that of Director of the Division of Emergency Medical Services in Virginia.

The National Association of State Emergency Medical Services Directors is composed of the director of the lead emergency medical services agency in each state, the District of Columbia, and the U.S. territories. Each of these agencies has the responsibility for the development of emergency medical services in their respective state or territory, as well as for licensing and inspecting ambulances, certifying emergency medical services personnel, and other activities related to maintaining minimum standards for prehospital emergency care.

As an Association, one of our purposes is to ensure continued support for the ongoing development of emergency medical services by working with the federal government. It is in this vein that I want to take the opportunity to present our views on the appropriations for the Preventive Health and Health Services Block Grant Program of the Department of Health and Human Services, now being considered by your Subcommittee.

Our Association has a very strong commitment to the continuation of comprehensive EMS system programs in the United States in order to prevent death and disability, thousands of times daily, throughout the nation. The early 1970's saw the passage of the Emergency Medical Services Act which heralded a major national effort to improve emergency medical services in this country. This program, administered by the Department of Health and Human Services, supplemented the ongoing work of the Department of Transportation. The changes stemming from this national movement are evident to some degree in virtually every commmunmity across this country.

With the replacement of this categorical grant program by the Preventive Health and Health Services Block Grant Program in 1981, the Emergency Medical Services Program suffered a substantial reduction in federal support, both in terms of funding and program leadership. In FY 86, less than $15 million, approximately 16 percent of the total Preventive Health and Health Services Block Grant, was allocated to emergency medical services. Ten states received no money for EMS from this Block Grant and in many states the level of support is progressively dwindling.

We would urge continued funding of the Preventive Health and Health Services Block Grant at at least its current level, but would further urge that adequate funding be provided for both the preventive and the health services aspects that must be addressed to effectively serve the citizens of this nation.

The National Association of State Emergency Medical Services Directors also believes that the flexibility of the block grant programs must be maintained in order to permit states to use this funding in relation to the emergency medical services needs and priorities that exist in each state now and in the future.

The Subcommittee on Labor, Health, Education, and Welfare is urged to act favorably to continue the Preventive Health and Health Service Block Grant Program and to ensure that adequate funding is provided in order that emergency medical services systems throughout the nation are kept viable to be able to further reduce death and disability resulting from sudden illness and serious injury.

National Association of State Emergency Medical Services Directors
Preventive Health & Health Services Block Grant Funding
FY 86

State	Total Prev. Health Block Grant Allocation	Prev. Health Block Grant Monies Allocated to EMS	Percent of Total
Alabama	$ 1,504,730	$ 257,000	17.1
Alaska	326,890	50,000	15.3
Arizona	1,089,835	100,000	9.2
Arkansas	844,454	30,000	3.5
California	6,320,373	1,800,000	28.5
Colorado	1,153,056	100,000	7.2
Connecticut	1,379,453	170,000	12.3
Delaware	173,300	-0-	0
Dist.of Columbia	743,890	18,000	2.4
Florida	2,722,585	-0-	0
Georgia	2,894,030	100,000	3.4
Hawaii	743,827	210,000	28.2
Idaho	346,443	42,000	12.1
Illinois	2,209,214	-0-	0
Indiana	1,586,101	250,000	15.7
Iowa	1,047,495	240,000	22.9
Kansas	890,353	-0-	0
Kentucky	1,270,572	-0-	0
Louisiana	2,779,436	848,000	30.5
Maine	853,644	398,886	46.7
Maryland	1,777,482	196,000	11.0
Massachusetts	2,582,426	1,040,000	40.2
Michigan	3,757,928	177,000	4.7
Minnesota	2,403,615	602,000	2.5
Mississippi	1,385,659	249,000	17.9
Missouri	2,368,008	480,000	20.2
Montana	632,187	185,439	29.3
Nebraska	1,594,861	350,000	21.9
Nevada	348,687	41,000	11.7
New Hampshire	1,365,676	700,000	51.1
New Jersey	2,735,859	300,000	10.9
New Mexico	1,336,564	730,000	54.6
New York	6,540,843	1,080,000	16.5
North Carolina	2,574,170	250,000	9.7
North Dakota	243,687	-0-	0
Ohio	4,311,614	52,000	1.2
Oklahoma	884,352	280,000	31.6
Oregon	669,502	54,329	8.1
Pennsylvania	4,543,342	905,000	19.9
Puerto Rico	1,484,615		
Rhode Island	451,828	-0-	0
South Carolina	1,154,336	190,000	16.4
South Dakota	220,231	-0-	0
Tennessee	1,525,908	55,000	3.6
Texas	3,731,712	700,000	18.7
Utah	905,016	151,900	15.8
Vermont	259,151	-0-	0
Virginia	1,907,873	100,000	5.2
Virgin Islands	166,727		
Washington	921,769	-0-	0
West Virginia	859,607	593,000	68.9
Wisconsin	1,854,342	100,000	5.4
Wyoming	216,550	110,000	50.8
Totals	$88,595,808	$14,285,554	16.0

STATEMENT OF JEFFREY LEVI, DIRECTOR OF GOVERNMENTAL AND POLITICAL AFFAIRS, NATIONAL GAY TASK FORCE

Mr. Chairman, I am testifying on behalf of the National Gay and Lesbian Task Force, the oldest national gay/lesbian civil rights advocacy organization. Since the beginning of the AIDS crisis we have been privileged to work with you and this committee to help solve this terrible medical mystery and assure adequate education, treatment and services for those affected by AIDS. Your leadership has been essential to the tremendous progress we have made to date, especially in light of the Administration's consistent resistence to providing adequate funding for this struggle.

We cannot allow our concern about AIDS to diminish. The number of AIDS cases continues to rise at an alarming rate. When I testified before this committee last year there were 10,000 cases, now there are over 18,000. We are only beginning to recognize the needs of those millions more who have AIDS-related conditions or are infected with HTLV-III. We are also witnessing the nationalization of the disease: it is no longer concentrated in a few geographic areas. More and more communities must be assisted in coping with this public health crisis. As I travel across the country, I find that we are unfortunately moving to a two-class system of access to care and services for persons with AIDS. Those living in high-incidence communities have access to research protocols and model care facilities while elsewhere increasing numbers of persons with AIDS are relegated to levels of care that are months or years behind our medical knowledge and capabilities.

There can be no doubt about the tremendous scientific progress that has been made during this crisis. But with each advance, more and more avenues are opened for additional exploration. For example, as a drug moves through the various stages of trials, the number of individuals involved in those trials increases. Thus, each advance in finding a potential drug therapy requires additional resources.

This makes all the more cynical the Administration's proposal for recisions totalling $41 million over the Gramm-Rudman-Hollings cuts. We commend the Congress for rejecting this move as it would have crippled some of the critical components of the fight against AIDS: cutting basic research at NIH, eliminating demonstration health care programs, and abolishing alternative testing sites at a time when the Public Health Service is calling for increased HTLV-III antibody testing.

We believe a significant increase in PHS AIDS funding for fiscal 1987 beyond the $244 million appropriated in 1986 will be essential to maintain the level of progress we are making and to meet our responsibility to provide for those who become ill. There is a range of areas that require additional attention. These include:

o Expanded education programs to teach individuals in high-risk groups how to prevent transmission of the HTLV-III virus and to train health care professionals how to treat and counsel those affected by the disease. The focus of these efforts must be broader than in the past, to include in particular adolescents, I.V. drug users, and those in low-incidence communities where awareness about AIDS may still be low. This money would be well invested: if prevention activities saved 2,600 individuals from developing AIDS, we would save $400 million in health care costs alone.

o Expanded clinical trials of therapeutic drugs to assure that the entire range and combinations of anti-virals and immune stimulators are fully explored and to assure greater access to these trials for persons with AIDS.

o Expansion of the non-hospital-care demonstration projects to low- and middle-range incidence communities. $16 million was first approved this year for high-incidence localities. If such demonstration programs can reduce the cost of care as dramatically as San Francisco's model has (where the cost of care averages $35,000 instead of the national average of $140,000), then the savings in the federal share of Medicaid costs alone would pay for such programs many times over.

o Research into the epidemiology and natural history of AIDS-related conditions (ARC) is essential to gain a better understanding of the course of the HTLV-III infection and what can be done to care for and possibly halt the progress of the disease. We do not fully understand the scope of the ARC problem. While not a fatal condition, ARC is chronic and its impact on the lives of those affected and the associated burden on the health care system are issues that must be addressed.

In addition to providing adequate funds for the AIDS budget, it will be essential to restore funds to those parts of the CDC and NIH budgets that have been diverted from other activities to meet the AIDS emergency. One of the more self-defeating diversions has been from sexually-transmitted disease prevention at CDC. We are told that between 15 and 30 percent of the 1986 STD budget has been spent on AIDS. This has contributed to a continued growth in certain sexually transmitted diseases, including many that are fatal. It also has denied health educators an opportunity to reach those who do not perceive themselves to be at risk for AIDS with a prevention message--one that would also protect them from infection with HTLV-III.

This is just a sampling of some of the additional work that needs to be done to address this crisis in the coming fiscal year. Figures proposed before the House Budget Committee have documented a need for between $390 and $400 million. We think that such an amount would begin to meet the full range of needs this growing medical and social crisis will demand in the next fiscal year. We recognize that Congress faces ever-tightening fiscal constraints. But the battle to save lives must continue. If waged effectively, this effort will save the federal government in direct Medicaid costs now and in similar costs later as the progress of the disease is halted. Delay will be counted in lives and care costs that will be a tragedy for this nation.

We hope we can count on your continuing leadership as our nation faces this difficult challenge. We look forward to working with you through this new appropriations cycle to assure further progress against this disease.

STATEMENT OF ROBERT A. DENMAN, LEGISLATIVE ASSISTANT, NATIONAL FARMERS UNION

We appreciate the opportunity to present testimony to the Subcommittee on Labor, Health and Human Services in support of FY 1987 appropriations for the Senior Community Service Employment Program, Title V of the Older Americans Act.

National Farmers Union is proud to continue 20 years of sponsorship of the Green Thumb program which provides employment opportunities for older, economically disadvantaged men and women in the rural communities in which they reside across the nation. In 1965, National Farmers Union proposed to take the green thumbs of older and retired farmers and put them to work to beautify our highways. These were people who had been caught in the backwash of a revolution in agriculture and a migration of young people to jobs in the cities. They had little or no Social Security coverage because farmers were not brought under the program until 1955 and earnings were often low. But, they did have a lifetime of experience and a commitment to work and use their skills productively.

From that small beginning, we have expanded the variety of jobs from parks and trails and highway reststop projects to provide enrollees with opportunities to help rural schools in the education of young people, to help with transportation needs for older, isolated rural citizens, and to help in small towns, nursing homes, libraries and senior citizen centers.

Another of Title V's objectives is to encourage unsubsidized employment for their enrollees, with better wages and more hours and fringe benefits. When needed, they provide training and work experience as need is determined through periodic individual assessment.

We must report that farmers are experiencing troubled times. Low farm prices and related problems have driven thousands of farm families from their life's work in the last few years. Economists predict that 10% of this nation's farmers will be driven from farming in the next two years, according to a December 24, 1985, article in the Wall Street Journal. Twenty percent are in deep trouble with a rippling effect of $25 billion farm-loan default and $30 to $50 billion cumulative reduction in real GNP over the next 8 years impacting in the whole national economy.

Green Thumb now is trying to help bankrupt farm men and women and their neighbors who meet Title V eligibility find a place earning a small weekly check to buy groceries and shoes and gas for the car. These people need help in beginning new careers, training and job placement that can build on the lifetime skills of "just a farmer."

Mr. Chairman, we are grateful for the interest and support which you and members of this Committee have shown to the Senior Community Service Employment program over the years. Increases in funding levels -- sometimes generous though not overly large in relation to need -- have made it possible to expand the opportunities for older workers, to extend services to their communities and supplement their own limited income. Although the program may seem small in relation to the eligible population, it produces a large multiplying effect in service to the communities it serves.

Improved health, longer life expectancies, dramatic changes in the workplace and the aging of the post-World War II "baby boom" generation have forced a new look at older workers, according to the Ninth Annual Report on Older Workers by the National Commission for Employment Policy. For most older workers, age is an advantage, but for some 5 million, or 10%, of today's older workers the picture is not so good. Older workers who lose their jobs, or are members of minority groups, as well as many older women and those older workers who have health problems, often face serious problems in the labor market.

Green Thumb has always endeavored to reach out to those most in need of an opportunity to work, and many of them had limited chance for education and training. There were 18,478 older workers enrolled in Green Thumb at the end of the last grant year, June 30, 1985. Half of them were between 60 and 70 years of age, and almost a fourth were over 70; 86% had family income below the poverty level. Over 7,000 had an 8th grade education or less, 4,017 attended 9th to 11th grade, and 5,387 more completed high school. Women made up 61% of the enrollmen and 18% were minorities.

The Senior Community Service Employment Program will suffer the 4.3% cut in funding mandated by the Gramm-Rudman-Hollings Balanced Budget Amendment when grants are executed by the Department of Labor on July 1, 1986, to commit the FY 1986 appropriations for Title V. This cut in funding will be absorbed through attrition of enrollees who leave the program for unsubsidized jobs, or retire from their assignment. This will, of course, mean a reduction of service to the community organizations and local branches of government who at the same time are suffering funding cuts from other sources. While we hope it will have the least disruptive impact on those workers who have found it necessary to supplement their limited income, it will also further limit employment opportunities to the thousands of eligible men and women who need the opportunity to work.

Green Thumb continues to make every effort to reduce the administrative costs of operating the program and has been successful to the degree that they will put as much of their new grant in enrollee wages next year as was going to workers four years ago, even with the Gramm-Rudman 4.3% cut in funding. They will continue to look for administrative efficiency, but it must be recognized that the continued high quality of a program does require supervision by skilled and experienced staff to maintain the broad mandate of the Senior Community Service Employment Program.

Title V is an employment and training program and a major purpose is to train older workers for better jobs. It is intended as a means to an end. It is a new beginning. In addition to the on-the-job training that enrollees receive while working with their host agencies, our Green Thumb staff helps them find opportunities for training and development which will enhance their performance and help better prepare them for their community service jobs as well as placement in unsubsidized jobs.

Congress directed that 3% of the funds appropriated for Title V be made available for experimental training programs to help older workers move into jobs in private industry. Green Thumb has carried on several such projects, one of which has focused on training older workers as health care para-professionals in order to work in nursing homes or provide vitally needed home health care which appears to be one of the most rapidly growing areas of demand for trained personnel. Such training programs can be replicated by other organizations through the help of a handbook which Green Thumb developed from their experimental programs.

In the interest of expanding the numbers of opportunities for older people needing employment, we have actively reached out to work with the Job Training Partnership Act (JTPA) at the local and state level. Congress directed that 3% of the JTPA funds be targeted toward expanding employment opportunities for older workers in the private sector, and Green Thumb has been anxious to cooperate in making use of those funds for productive opportunities for older people in the communities in which Green Thumb projects are located.

In several states, Green Thumb has been asked to administer a part of those funds. In many other cases, we have actively promoted coalition activities that will make the most productive use of the resources of both JTPA and the Senior Community Service Employment Program. We find that they can complement one another because JTPA by and large cannot provide stipends to help older workers while they attend extended training courses, and Title V is complemented by the classroom training resources that can be made available through JTPA. Green Thumb and JTPA have also cooperated on recruitment, follow-up and placement assistance to help both employers and workers.

We are actively seeking ways in which to complement the work of the Job Corp in those areas where they have training centers. The Assistant Secretary of Labor has directed that older workers be utilized in areas of supportive training so that they can serve as role models for the younger workers. We believe it can be a most productive effort and builds on a Green Thumb demonstration program some years ago of a younger worker/older worker employment training program that was also funded by the Department of Labor.

We were glad to note that the Reagan Administration included in their FY 1987 budget the sum of $326 million for the Senior Community Service Employment Program.

While we have focused our testimony on the Senior Community Service Employment Program, we want to emphasize the importance of continued funding, at least at current service levels, for all titles of the Older Americans Act. The support and coordination of the aging network must be maintained to assist a rapidly growing older population.

Almost one-third of Green Thumb workers furnish services to the elderly. Over 1,900 work in nutrition programs and 1,285 serve in senior centers, while more than 500 provide health and home care and an equal number fill needed services through outreach and referral to community agencies. Over 350 help in vital transportation services. Reductions in funding for other programs under the Older Americans Act are immediately reflected in increased requests for help from Title V enrollees to assist in unmet service needs.

We urge, that in consideration of FY 1987 funding, you make every effort to maintain the current services funding level which recognizes an inflation factor for the Senior Community Service Employment Program and other Older Americans Act programs so that Green Thumb and others administering this program can continue to find new ways to meet community needs through host agencies and help older workers with the employment training they need to move on to being productive, tax-paying members of their communities, WORKING HARD, WORKING WELL, AND WORKING PROUD.

STATEMENT OF DR. TIMOTHY TALBOT, FORMER CHAIRMAN OF THE BOARD, ASSOCIATION OF AMERICAN CANCER INSTITUTES

Senator PROXMIRE. We have a couple of cancellations. We come to Dr. Timothy Talbot, former chairman of the board, Association of American Cancer Institutes.

Good morning.

Dr. TALBOT. Good morning, Mr. Chairman. I will try to be brief, Mr. Chairman, since you already know most of the facts as well or better than I do. But I first want to thank you for giving us the opportunity to present to you the concerns of the Association of American Cancer Research, which includes all of the major cancer centers of the Nation.

I am Dr. Timothy Talbot, president emeritus of the Fox Chase Cancer Center, and former chairman of the board of the Association of American Cancer Institutes.

I am sure that you are aware that the cancer centers of the Nation have not fared very well under the President's proposed budget and that we might well have suffered five separate, important hits during this decreasing Federal support.

Of course, the first was sequestration; the second was rescissions, which you and your committee did not permit, thank you; the third results from the proposed fiscal 1987 budget, which is lower than that, is even less than the budget of 1986, even after the cuts; and then there is another problem, because it is understood that in the fiscal 1987 budget year, that will cause noncompeting cancer centers to have a 5-percent reduction from current levels and committed levels, whereas competing centers will be reduced by 25 percent from recommended levels. The thing that I want to emphasize there is the inequitability of that.

The fourth resulted from the proposed regulations regarding indirect costs, which I would like to dwell on for a moment, because it is something that I think the current proposal ought to get the Golden Fleece Award for. Of course, the problem is that very few people understand the indirect cost problem. It is an extremely complex one that few people really grasp. As you know, there is manual A–21 and there is manual A–122, which some cancer centers operate under.

This, therefore, leads to another problem of great inequity; if the A–21 rules are enforced, that means the A–122 people, which includes our institution, won't get hurt yet. But others will. I have no doubt that if the A–21 recommendations go through, that that will follow.

The fifth will result from the likely sequestration under the second year of Gramm-Rudman. We are particularly concerned and upset that it has been indicated to us that there may be as many as four or five cancer centers which will be completely defunded in fiscal year 1986 because of the sequestrations and cutbacks. That makes no sense to us, and probably not to you.

Additionally, budgetary confusion has been added by the transfer of the Office of the Assistant Secretary for Health of approximately $27 million for AIDS research. I agree with the testimony of Mr.

McDonald, who testified just a few minutes ago, regarding the funding of AIDS in that regard. The leadership and management of Dr. DeVita has been outstanding. He does not need exterior micromanagement. What he and we do need is flexibility. He has allocated his funds wisely, and we urge that he not be hobbled and restricted.

This is especially important during times when money is tight and experienced judgment becomes ever more critical. I hope that this will be given some attention, although I know it is a difficult problem. We have some specific recommendations to make, Mr. Chairman.

First, it is clear that the Congress and this committee have been remarkably careful and, I think, loyal in their support of biomedical research, and I think wisely so. We think that the current authorizations for fiscal year 1987, which amount to $1.34 billion, are a sensible target, which have been arrived at over 3 years of careful compromises between the Senate and the House.

We are aware, of course, that the bypass budget recommends a level of $1.5 billion, but we can hardly avoid recognizing that the Congress has set a ceiling on the authorization of appropriations at $1.34 billion, and we want you to know that we support that level. There cannot be sacred cows, but there should be no foolish sacrifices.

Also, with regard to indirect costs, we recommend that this committee urge an immediate study of the matter by an independent, highly qualified team, perhaps drawn from the field of public policy and from fiscal analysis/management, who are not allied with the Office of Management and Budget or with the research community, in order to make recommendations regarding the entire subject of indirect costs.

Naturally, we would urge consultation with the appropriate parties, universities, and centers. Finally, we support the Ad Hoc Coalition for Biomedical Research's suggestion of a $6.07 billion overall NIH budget.

You are undoubtedly aware that the National Coalition for Cancer Research has been formed. We are members of that, the Association of American Cancer Institutes. The gentleman who will follow me, Dr. Owens of Johns Hopkins and his association that he represents, is also a member. We have found this to be a very effective and, I think, useful organization which contributes to our joint wisdom immeasurably.

Mr. Chairman, my final word is that cancer centers have made a big difference. They will continue to do so if they are not strangled.

Senator PROXMIRE. Doctor, I want to thank you very, very much for your fine statement. All of us recognize what a very, very important responsibility you are assuming and how vital and critical it is that the Federal Government be as generous as we possibly can.

In your statement, you dwell on attempts to implement across-the-board cuts in indirect costs. Such costs used to consume 20 percent of each research dollar. Now they consume one-third of each research dollar. Are you concerned about indirect cost growth? Are there any answers to it?

Dr. TALBOT. Yes; I am concerned about it, but the problem is, Mr. Chairman, that the complexity of the rules and the complexity of accounting systems has led to this apparent discrepancy, and it isn't really what it seems to be. For example, a State-supported university is entirely different in its allocations than an institution such as ours. And there are massive variations in the entire system.

I think what we need to do is to throw A–21 away and start over, because until we get this manual to define in reasonably precise terms what is allowable and what isn't, and how it floats all over the place, we will never have a handle on it.

Senator PROXMIRE. I appreciate that response very, very much. We would very much appreciate any recommendations you can make in detail on that score.

Dr. TALBOT. We could probably do that, sir.

Senator PROXMIRE. These days, when we have such colossal pressure, as you know, to hold down spending and hold down the deficit, whatever we can save I think we can put to constructive use.

Dr. TALBOT. My concern is the inequitability that that ruling would enforce upon many institutions, and it is inequitability that I am focusing on.

If an across-the-board cut of a percentage reduction is made, some people will suffer greatly and some won't, and that is the problem.

PREPARED STATEMENT

Senator PROXMIRE. Thank you, sir.

Dr. TALBOT. Thank you, sir.

[The statement follows:]

STATEMENT OF TIMOTHY R. TALBOT, JR.

Mr. Chairman and Members of the Committee, thank you very much for giving us the opportunity to present to you the concerns of the Association of American Cancer Institutes, which includes all of the major cancer centers in the nation.

I am Dr. Timothy R. Talbot, Jr., President Emeritus of the Fox Chase Cancer Center in Philadelphia, and former President and Chairman as well as a founding member of the AACI.

Mr. Chairman, I have appeared before you for several years, on behalf of appropriations for the National Cancer Institute in general, and the cancer centers of the nation in particular.

I am sure that you, faced with many attempts to reduce funds for the biomedical research of this nation, are as weary and frustrated at the process as are we. We deeply appreciate your constant, unrelenting attention to this matter, and wish you to know that we understand the enormous amount of energy that you and your Committee have put into fighting to keep the biomedical research enterprise of the United States moving forward as rapidly as possible.

The cancer centers of this nation have not fared well under the President's proposed budget for FY 1987.

I would like to relate to you the fact that during this year we might well have suffered five separate "hits", decreasing Federal support for research in cancer centers.

The first was the first year "sequestration" under Gramm-Rudman-Hollings, which has already taken effect, resulting in a 4.3% decrease for centers, and every other line in the budget. (The total sequestration for NCI was $53.8 million.) Some centers will suffer more than others, as the sequestration order did not take place until well into the fiscal year. Thus, we have another example of inequity.

The second was the proposed "rescission", which you have not permitted, which would have resulted in an additional $6.3 million cut from the overall NCI budget, which would also impact on cancer centers.

The third results from the FY 1987 proposed budget, which is lower than that of FY 1985 and 1986 (even after the above cuts are made for FY 1986), and would cause a further decrease in support for the centers.

In this regard, it is understood that the FY 1987 budget proposal will cause non-competing centers to have a five percent reduction from commitment levels, and competing centers will be reduced by 25% from recommended levels, compared to a 20% reduction in FY 1986. Yet another example of inequity.

This in spite of specific Senate bill report language which required that the NCI should, within budgetary constraints, fund cancer centers at the peer reviewed levels that they had been assigned (see the Senate bill report language attached to this statement).

The fourth results from the proposed regulations which would cut back the indirect costs of research grants, across the board for those centers that operate under the rules of manual A-21. Some cancer centers operate under manual A-21, while others operate under A-122. This is, therefore, yet another example of gross inequity, because of the differences resulting from A-21 rules as opposed to A-122 rules. Thus, some cancer centers would be hurt severely if this proposal is accepted. (We strongly support the House language in the urgent supplemental appropriations bill to be considered soon by the House, and shortly after by the Senate, which would prevent this regulation from taking effect until September 30, 1986, giving the Congress time to study and then to deal with the matter.)

The fifth will result from the likely sequestration under the second year of Gramm-Rudman-Hollings.

Mr. Chairman, in spite of the fact that you have turned away the Administrations's proposed rescission, we will nevertheless be taking four "hits" this year. But we will be taking them with great inequitability. That is wrong.

We are particularly upset that it has been indicated to us that there may be as many as four or five cancer centers which will be defunded in fiscal year 1986 because of the sequestrations and other cutbacks. After we have spent so much time over the years developing excellent centers, we now find that some will be "defunded". We believe that is particularly unfortunate, especially at a time when the Congress has indicated its intention that more cancer centers, not less, should be developed to serve the nation both in research and patient care.

IMPACT OF CUTS ON THE NCI

Mr. Chairman, as you know, the NCI suffered a very severe cutback, because of the sequestration order, to the tune of $53.8 million in the fiscal year 1986 budget. Happily you did not agree to a $6.8 million rescission. Additionally, budgetary confusion has been added by the transfer to the Office of the Assistant Secretary for Health of approximately $27.2 million for AIDS research - this is another way of wrecking what is already working.

Nevertheless, when one analyzes the "bottom line" one sees the following figures emerge for NCI.

Fiscal year 1985:	$1,163,736,000
Fiscal year 1986:	$1,177,475,000
Fiscal year 1987:	$1,158,089,000

(It should be noted, Mr. Chairman, that the fiscal year 1986 figure would have been $1,170,000,000 had not the Committee fought the proposed rescission.)

Nevertheless, the result is that there is a serious drop for research in the field of cancer from fiscal year 1986 to 1987, and in fact the fiscal year 1987 figure is even below that for fiscal year 1985.

These decreases are also far more serious than would be indicated by the influence of inflation, because the essential costs of cancer research have risen at a rate that is considerably higher than that. The result is that we have fallen behind at a rate that exceeds about 11%.

We are presented with this cutback at a time when the advances in biomedical research, largely assisted by the cancer center program, have been burgeoning.

I will not go into detail on all of the advances that have been occurring. We have read with care the testimony of Dr. Vincent DeVita, Director of the National Cancer Institute. We know of the great support that you gave to Dr. DeVita in his work, and to the national biomedical community, during the time that Dr. DeVita appeared before your Committee.

RECOMMENDATIONS

We have some recommendations to make, Mr. Chairman, and they are very simple.

First, it is clear to us that the Congress of the United States has a profound respect and support for biomedical research. This was evidenced by the 10-1 vote by which the President's veto was overridden on the biomedical research authorizations bill late last year. There were authorizations of appropriations for FY 1987 in that bill which amounted to $1.34 billion. We believe that that is a sensible target arrived at over three years of careful compromises between the Senate and House on the level of cancer research funding that should be attempted.

We support the Congress wholeheartedly in this authorization of appropriations level. That is the recommendation we make to you now.

We understand that many professionals were involved in the development of the congressionally mandated "By-pass Budget", which recommends a level of $1.5 billion. We in the field believe that there is enormous room for growth, enormous opportunity available for us to advance our understanding of the diseases known as cancer, and would far prefer to support the higher budgetary level. We do recognize, however, that the Congress has set a ceiling on the authorization of appropriations at $1.34 billion, and we want you to know that we support that level. There can be no sacred cows, but there should be no foolish sacrifices.

Also, with regard to indirect costs, we recommend that this Committee urge an immediate study of the matter by an independent, highly qualified team of persons, perhaps drawn from the field of public policy and from fiscal analysis/management, who are not allied with the OMB, or with the research community, to make recommendations regarding the entire subject of indirect costs. Naturally, we would urge intimate and detailed consultation with the affected parties. Unhappily, nearly all previous proposals have come from either OMB or the research community. We know that if Circular A-21, which affects most of the cancer centers (since most are university connected), is being considered for revision, that Circular A-122 which deals with "free-standing" institutions, and which would include about 15 cancer centers, will be prepared for revision next. We hope you will consider this recommendation on indirect costs favorably. It is our belief that A-21 and A-122 should be thrown away, and that simple straightforward definitions of indirect cost eligibility should be set forth in an uncomplicated set of easily comprehended factors, with uniformity of eligibility in those categories. No other solution can be equitable or effective.

Finally, we support the Ad Hoc Coalition for Biomedical Research's suggestion of $6.07 billion overall for NIH in FY 1987.

Mr. Chairman, my final word is that cancer centers have made a difference-they have had an impact that sparked the beginnings of a major new effort. They will continue to do so if they are not strangled. And I'm sure that you know why - it is because these centers believe that it is their purpose to do so.

I will be pleased to answer any questions you may have.

SUMMARY OF FISCAL HISTORY

NATIONAL CANCER INSTITUTE APPROPRIATIONS FOR FY 1985, 1986, 1987

	1985	1986	1987
Appropriation	$1,183,806,000	$1,258,159,000	$1,158,089,000
Enacted supplemental	3,000,000		Administration's Proposed Budget
Enacted administrative reduction		-922,000	
Sequester order		-53,868,000	
Proposed rescission		-6,800,000	

(And less transfers and administrative adjustments, including transfer in FY 1985 and FY 1986 of about $27.2 million for AIDS research transferred to the Office of the Assistant Secretary for Health.)

	1985	1986	1987
TOTAL OBLIGATIONS	$1,163,736,000	$1,170,475,000 (without proposed rescission - $1,177,000,000)	$1,158,089,000

SENATE APPROPRIATIONS BILL REPORT LANGUAGE FOR FY 1986 RELATING TO CANCER CENTERS

"While the Committee continues its unequivocal support for basic research, it also realizes that other areas are integral to the effort to conquer cancer. Cancer centers and clinical cooperative groups, for example, are vital national resources and must continue to receive adequate support. In its fiscal year 1985 report, the Committee noted its concern that cancer center core grants had been treated differently from other grants and have been decreased on the average of 15 percent below peer-reviewed levels, and indicated its desire that these core grants be funded at full peer-reviewed levels. The Committee has learned that this instruction was interpreted to mean that only new and competing grants should be funded at peer-reviewed levels (these were funded at 95 percent of such levels), but that non-competing continuation awards were funded at the 85 percent level, as they had previously. The Committee desires that all such core grants, competing and non-competing, should, within budgetary constraints, be funded at the peer-reviewed levels they had been assigned."

STATEMENT OF DR. ALBERT OWENS, DIRECTOR OF THE JOHNS HOPKINS ONCOLOGY CENTER AND ON BEHALF OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Senator PROXMIRE. Our next witness is Dr. Albert Owens, director of the Johns Hopkins Oncology Center on behalf of the American Society of Clinical Oncology.

Dr. OWENS. Thank you very much, Senator Proxmire.

Our society that I represent this morning is the largest one that is concerned with the professional people involved in cancer research and treatment. One-half of our membership is in the community treating, and the other one-half, roughly, are members of cancer centers and universities throughout the country.

I think one thing that we would like very much to do is to express our appreciation for Senator Weicker's and this committee's leadership in supporting biomedical research, especially at a time when our country faces very severe budgetary problems. We were very, very encouraged by the appropriations bill which came out last year. Unfortunately, I think our concern this year is that despite a very unambiguous congressional mandate, the funding that was made available to the Cancer Institute in 1986 was substantially below the 1985 level, and what we see in the administration's proposal for 1987 is reduced even further.

I think our main concern is that the enterprise will suffer greatly if we don't do something about it.

Senator PROXMIRE. Let me just interrupt. I think you are absolutely right. Lowell Weicker is a real star in this area. I don't think there is anybody in either party in the House or the Senate who has been so deeply concerned and so effective in providing adequate funding for the National Institutes of Health.

Dr. OWENS. And we appreciate it very much, and we wish Senator Weicker's current amendment well. We have tried to do what we can to support it.

One of the things that we have done in our last discussions in the last couple of years is focus on the number of research grants, and one thing I would like to do this year is to bring up the notion that if we are going to put science in human service, there is a continuum that goes all the way from ideas to applications, and like a chain, its strong is its weakest link.

I think we ought to focus on the entire process and try to do what we can to keep it strong and in balance.

If we look at the funding or the impact of the funding restrictions, we are down to funding only 27 percent of our approved research grants in the cancer area; we are talking about funding cancer centers at 25 percent below their peer-recommended level, and there may be five or so whose grants are expected to terminate.

We are looking at clinical trials and organ site programs at 20 percent below prior years' levels, and we are looking at clincal education grants that are to be reduced by up to 50 percent and some of the other training grants by 10 percent or more; and construction grants are eliminated.

When we look at our premier cancer center, if you will, the National Cancer Institute, we see very effective direction being hobbled by the micromanagement which Tim Talbot referred to, by personnel position restrictions that are sort of straightjacketing him and making him, as we see it, progressively unable to use what resources are available to follow the best leads that are possible.

I think without prolonging and using your time unwisely, we would like very much to urge support of the Ad Hoc Coalition for Biomedical Research's funding level of $6.1 million. We would like to support very strongly last year's congressional authorization for the National Cancer Institute, have that matched by an appropriation this year of $1.34 billion; and we would like to thank you very, very much for your continued support and let you know, as Dr. Talbot did, that we are members of the coalition.

We have talked about this, and we are all together on this, I think, in terms of thanking you and urging you onward.

Senator PROXMIRE. Thank you very much, Dr. Owens. I understand, under the administration's budget, no new clinical trials would be started in 1987; is that correct?

Dr. OWENS. I believe that is correct, and I believe some of the clinical groups that are involved in this work have also been terminated or are in the process.

So there is a retraction. It is not just no new trials.

PREPARED STATEMENT

Senator PROXMIRE. We will do our best to overcome that. Thank you so much for your fine presentation.

Dr. OWENS. Thank you.

[The statement follows:]

STATEMENT OF ALBERT H. OWENS, JR.

Mr. Chairman, I am Albert H. Owens, Jr., M.D., Director of the Johns Hopkins Oncology Center in Baltimore, Maryland. Also, I serve there as Professor of Oncology and Professor of Medicine.

Today I appear before you on behalf of the American Society of Clinical Oncology (ASCO). I am Chairman of the Public Issues Committee and a former President of ASCO.

Although I am sure that you will recall information about our organization, I would like to supply some of it for the record, to place our concerns in perspective regarding the fiscal year 1987 proposal for the NCI budget by the Administration.

The American Society of Clinical Oncology was founded 20 years ago and has become the nation's largest organization of specialists involved in providing cancer patient care, conducting clinical cancer research and training cancer physican specialists. Members of this Society are involved directly, or as consultants, in the care of the majority of the cancer patients in the United States. Its members include the nation's leading physicians in medical oncology, pediatric oncology, radiation oncology, surgical oncology, gynecologic oncology, and also basic scientists in pathology, immunology, pharmacology, biostatistics, and other areas of basic biomedical science. Collectively, this Society represents the nation's major resource of specialists in the diagnosis and treatment of cancer patients, the application of research to cancer patients and the training of the cancer physicians and clinical researchers of the future. Approximately half of its members are practicing physicians caring for the nation's cancer patients in their offices and in many community hospitals, and half are engaged in research and training in literally all of the nation's schools of medicine, cancer hospitals, centers and institutes.

OVERALL VIEW

Last year the Congress made a very strong statement in support of biomedical research at a time when it was also facing severe budgetary problems. Mr. Chairman, we appreciate your hard work to create a major increase in funding for the National Cancer Institute; the ensuing appropriations bill was an excellent one. In addition, when the Congress overrode the President's veto of the NIH authorization bill, it set very reasonable appropriation authorizations for cancer research at $1.34 billion.

Despite an unambiguous Congressional mandate, the funding made available to the National Cancer Institute in 1986 was substantially below the 1985 level. Further, the Administration's proposed budget for fiscal year 1987 will reduce it even further.

Fortunately, the cancer research enterprise in this country is burgeoning with discoveries of great potential benefit to the American people. Cancer research, by its nature, is a continuum which extends from ideas to application. This process is no stronger than its weakest link. Further, we would observe that the matter of reducing science to human service is highly dependent on the work of well-educated and extraordinarily dedicated people.

The 1986 funding of the NCI severely threatens the effectiveness of the cancer research continuum:

- Only 27% of approved research grants are funded
- Centers are funded at 25% below approved levels and the funding of 5 center grants is expected to terminate
- Clinical trials groups and organ site programs are budgeted at 20% of last year's levels and some groups are terminated
- Clinical Education grants are reduced by 50%; other research training by 10% or more
- Construction grants are eliminated
- The intramural NCI program is severely constrained; e.g., its present personnel positions are being held at 344 below 1985 levels.

If the Administration's proposed budget for 1987 is adopted, the situation will worsen to the point of devastation. Without adequate federal funding the cancer research enterprise cannot continue to be effective in meeting one of the nation's major health problems. For example, without adequate funding, sufficient cancer research grants will not be available to explore our best ideas and without appropriate funding for cancer centers and clinical trials groups, human disease research and treatment applications will be even more severely limited.

RECOMMENDATIONS

In brief, Mr. Chairman, ASCO would like to advance the following recommendations:

1. We support the Ad Hoc Coalition for Biomedical Research's funding level of $6.073 billion for the NIH.

2. We believe that last year's Congressional authorization for the NCI appropriation of $1.34 billion is most reasonable for an FY 1987 appropriation level.

2. We believe that it is imperative to maintain the effectiveness of this country's cancer research enterprise by restoring the funding of research grants,

centers, clinical trials groups, etc., to peer review approved levels, and to assure appropriate growth for those areas of research.

I believe that you will find all of the major organizations concerned with cancer research and treatment are in accord with these main points.

APPRECIATION

Mr. Chairman, please accept our heartfelt thanks for your continued support and know that we appreciate your courtesy in hearing us again this year.

STATEMENT OF GRACE POWERS MONACO, NATIONAL LIAISON CHAIRMAN FOR THE CANDLELIGHTERS (PARENTS OF CHILDREN WITH CANCER)

Senator PROXMIRE. Our next witness is Grace Powers Monaco, national liaison chairman for the Candlelighters.

Senator PROXMIRE. You are concerned with children with cancer, whose parents have organized as Candlelighters?

Ms. MONACO.Yes; and we provided a statement for the record that we would like to have printed in the record.

Senator PROXMIRE. It will be.

Ms. MONACO. I want to summarize our remarks. I want to give you greetings from the group that is the crown for the Milwaukee children and parents in Wisconsin as well as the Candlelighter Cancer Assistance Program that is there. With those two people's programs, we are dealing—it is in your State—with a lot of the psychosocial and economic problems that are a continuum of what a parent of a child with cancer is faced with.

What we are bringing home to you today is where the dollars need to be put in order to take care of that aspect, which is that we should not suffer from terminal ignorance. Unfortunately, occasionally that is a condition that can affect us when the funds are not appropriated appropriately to carry out these programs.

I have been testifying since 1970 for parents of children with cancer. When I started in 1970, we had three parent support groups in the United States. We now have 225. We are members of the coalition that has been referenced before, and we also wish to certainly ask you to please tell the OMB camel to keep its nose out of the NIH Director's tent.

If you in Congress are telling them you have an extra large amount of a pot of money to play with, go forth and do the best you can with it. To have OMB trying, by program lines, to wrest some of that money back and not permit it to be reallocated when breakthroughs are occurring or new opportunities are focused on, or if NIH, through NCI, sees a place in which they can cut back here in order to improve in funding somewhere else, it is an obscene and certainly a pernicious road that OMB is taking.

I think it is very sneaky, and I think it is certainly something that destroys a lot of the efforts that you gentlemen here at the Senate have certainly been supportive of in research for the period of time that I have been testifying.

Why do we as parents of children with cancer have to come here specifically and talk to you about money? We are the smallest part of the cancer problem in terms of the numbers that are affected. We have between 6,000 and 7,000 children diagnosed every year.

However, our area of cancer, pediatric cancer, has served as the laboratory for new developments in the application of research to the benefit of the adult patient community.

When I first started testifying, we were saying that approximately 50, we were hoping that approximately 55 percent of our children would be cured by the year 1985 or 1986.

Back then, in 1970, it was 39 percent. That has come true. It has come true because of the tremendous collegiality in the area of pediatric cancer. It has come through because indeed, if we want to look specifically at the way pediatric cancer research, the application of that research operates, it operates almost as if it was a national clinical cooperative group because we are small numbers, and we are able to keep track of what is happening.

Now, let me just give you a little insight into what is happening in pediatric cancer that should tell you that it is very important to fully fund, as my prior colleagues have suggested, the areas of centers, the areas of the clinical cooperative programs, and certainly, the NIH intramural program.

As Dr. Owens pointed out to you, that is, indeed, the crown jewel of most of what is happening in pediatric cancer research, particularly in the area of cytogenetics. Cytogenetics was a gleam in the eye in 1970. I would not have known what that word means. I am not sure at that time I would have cared or understood what it meant.

But I will say, just very briefly, that with what NIH is learning in cytogenetics, we are now, for example, in the area of being able to so finetune the subset of cancers that we have been able to take children who had neuroepithelioma and were being treated under a neuroblastoma protocol with very little hope of cure, switch them, because we knew more about the cytogenetics, into a Ewings sarcoma protocol, and we are now being able to project a cure rate of 60 percent in those children.

Senator PROXMIRE. How does that compare with previous experience?

Ms. MONACO. Dismal. It is an increase of 30 or 40 percentage points in terms of anticipated cure, just from finding a little switch, a little subset that can finally characterize it.

Senator PROXMIRE. Sixty percent can be cured?

Ms. MONACO. Yes; by basic research. Basic research has been able to point to those switches. We can pare down who can benefit from particular research protocols and programs as opposed to who couldn't before; that we can save children who are in bad prognosis groups that we couldn't deal with effectively before.

What we are dealing with now, in those areas of pediatric cancer, is going to make a great deal of difference in being able to cure more colon cancer and lung cancer patients. The children have been the laboratory, the clean table on which we can see exactly what happens in the genetics, the chromosomes, and the type of treatment that should be given. They were the beginnings of the combined chemotherapy program, and we want to be able to continue to serve that role.

Unfortunately, we are small, and sometimes when the money gets passed out, the little guys who can't speak loud get overlooked in the NCI process. I would certainly like to ask this committee to pay special attention to that when it is deciding where that money goes. It certainly tells Dr. De Vita, as he acknowledged at a President's cancer panel meeting just a few weeks, that the pediatric people in the area of cytogenetics were there first, were there in a much more orderly manner and are going to do the research that will make the difference in the adult community just in combined chemotherapy.

I would like you to remind him and nudge him a little bit so we can continue to be the laboratory and continue to make it worth your while, for the money you have spent on us will continue to save the lives of our children and then later, save the lives of the adult community.

Thank you very much for having us.

PREPARED STATEMENT

Senator PROXMIRE. Thank you. You are a remarkable witness. I am very, very impressed.

Excellent job. Thank you Ms. Monaco.

[The statement follows:]

STATEMENT OF GRACE POWERS MONACO

My name is Grace Powers Monaco. I am National Liaison Chairman of the Metropolitan Washington Area Candlelighters. This association serves as the legislative arm of an international volunteer coalition of 225 groups of parents whose children have or have had cancer in 50 states and Australia, Canada, Chile, Denmark, England, Finland, France, Germany, Greece, Guatemala, Holland, India, Indonesia, Ireland, Israel, Italy, Mexico, New Zealand, Sweden, South Africa, Spain and East Africa.

When I first testified before this Committee in 1970 this nation was in a crisis point in federal cancer research funding. At that time we were only projecting the ability to fund research project grants at 50%. Today in 1986, that funding rate for peer reviewed and ranked research grants is only 27%. With the ripple effect, this Committee can anticipate how far the proposed budget will set back cancer research and its application in treatment and prevention.

This dismal as the prospect of such diminished research grant funding is made even more dismal by a hooker thrown at National Institues of Health by Office of Managment and Budget fiat regarding the apportionment process.

Until 1985, OMB distributed or apportioned funds appropriated by Congress directly to each of the NIH Institutes. Under this approach the Directors of the Institutes had the flexibility to make do within the budgetary restraints by shifting funds among program mechanisms to accomodate promising or new avenues of opportunity.

This is no longer possible. OMB now apportions all 16 NIH appropriations to NIH as a whole and specifies the amounts to be distributed by time period, by major categories of NIH expenditure or mechanism, such as grant, contract, centers etc. and by numbers of awards within selected categories.

The Congress tells NCI what funds it will get, makes a few suggestions on special areas of emphasis if needed and say--get on with it, best good use of your countries money. OMB says you are bound by every nitpicking line in your proposed budget, if you find a way to cut A, your can't shift it to immediately start on implementing research in new breakthrough B, you have to give us that money back. Good for their bottom line, bad for the patients looking for survival from cancer.

Please tell OMB to get their noses out of the tent and give the Directors the flexibility to make the best use of our money as their scientific knowledge dictates.

Dr. De Vita's testimony before this Committee well portrayed the exciting scientific times ahead for cancer research and treatment. He omitted reference however to the most important laboratory for the discovery, development and implementation of curative cancer therapy - the pediatric cancer patient.

At the President's Cancer Panel meeting in Memphis on April 11 at St. Jude Children's Research Hospital which addressed"the molecular characterization of childhood cancers and its application to innovative approaches to cancer therapy" Director De Vita remedied that omission. Dr.De Vita stated that pediatric researchers had initiated work on the cytogenetic problems in cancer in an orderly fashion ahead of their peers working in adult cancer. This comes as no surprise.

It was this population that was the guinea pig for the combination therapies that are now translated into increasing cure and survival rates in adults. A study by Dr. Robert W. Miller and Frank W. McKay published in the Journal of the American Medical Association * tracked deaths from cancer among children under age 15 from 1950 to 1979. It showed in that period:

80% fewer deaths from Hodgkin's disease, a type of blood cell cancer;

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* JAMA: 251(12) 156-70) March 1984

68% fewer deaths from kidney cancer;

50% fewer deaths from leukemia and bone cancer;

32% fewer deaths from other immune system cancers; and

31% fewer deaths from all other cancers.

1970 survival rate overall for childhood cancer was 39%. Now over 54% are surviving their disease.**

It is this group that now serves as the guinea pigs for progress in fine tuning treatment programs and in attacking resistant cancers and residual tumors. Our children are the tabula rosa of cancer research unsullied by the bad habits and exposures of adult life, giving a clear view to the genetic and chromosomal contributors to failures or success.

The magnificient work of Dr. Janet Rowley and colleagues presented at the President's Cancer Panel has trageted chromosomal defects and changes in Acute nonlymphocytic leukemia. Due to this ground breaking work knowledge of where and why chromosomal translocations and the like take place, what they mean and what they do is laying the groundwork to target defective genes in treatment and spare healthy genes.

In childhood neuroblastoma, identification of c-myc gene amplification helps target poor prognosis cancers and single those out for more aggressive treatment as well as pick up the disease progress earlier for special attention.

This hallmark work will increase our knowledge of who may have predispositions to certain cancer to permit earlier diagnosis, treatment and potentially prevention.

Further, in selective productive therapies, research in proto-oncogene expression has revealed the genetic similarities bewteen neuroepithelioma and Ewings sarcoma. Prior to this discovery children with neuroepithelioma were treated under a neuroblastoma protocol.

** American Cancer Society Statistics 1984

Treatment under Ewings sarcoma protocol has lead to superior treatment results. Before treatment substitution neuorepithelioma was considered an usually lethal condition. Now these children are enjoying a 93% response rate and a 60% projected cure rate.

The cyto-genetic characterization of tumors is in its infancy but it is the key to matching treatment to disease with the best hope of success. Once again, our children are the laboratory and in collegiality these pediatric cancer researchers are sharing skills, probes, tumors across institutional lines to a common purpose.

It is anticipated that the work on proto-oncogenes which has gone forward in our unique pediatric cancer projects will soon be applied to identify treatable subsets of lung and colon cancer hitherto impossible.

From basic research to bedside to long term follow-up, our children are the unique laboratory for pediatric cancer centers of excellence, joined through cooperative clinical trial relationships including the pace setting efforts of the National Cancer Institute's intramural and clinical center programs in pediatric cancer. The efforts of these professionals are enhanced by the patient and family coping and education materials conceived by the Office of Cancer Communications.

The proposed budget would compromise the continued effectiveness of all these programs which have spelled the difference between cure and merely long term survival for many of our children.

Under the proposed budget:

Our clinical cooperative programs, pediatric and adult would be reduced 20%,

Our centers programs 25% and

The functions of the Office of Cancer Communications to directly translate survival skills during cancer to the patient and family populations would be amputated.

Our please to this Committee is:

To fully fund the cooperative and centers programs,at the level that peer review has found warranted,

To retain the financial base to permit Office of Cancer Communications to do the job needed and

To fully fund and support NCI's intramural research and trial activities.

Further, fully fund P01's the mechanism to translate research advances to the bedside.

Cooperative Clinical Research should be fully funded at $50,204,000

National Cancer Institute Intramural program should be fully funded at $194,847,000

Clinical Centers programs should be funded at $135,627,000

Office of Cancer Communications should be fully funded at $900,000.

Cancer biology should be fully funded at $258,686

Pre-Clinical Research should be fully funded at $176,801

Clinical treatment research should be fully funded at $180,807.

Mr. Chairman, Members of the Committee, on behalf of all these parents across the country, I should like again to commend the Chairman and the Members of the Committee for this many efforts and their understanding of our problems. Your dedication to the cause, the cure and the prevention of cancer encourages us to face the future with a greater degree of hope and peace of mind. Those of us who have lost children are grateful that your efforts to adequately fund the cancer research will be a memorial to them. And, those of us whose children are under treatment are grateful for the hope which research gives us in maintaining their well-being.

We gratefully acknowledge the part this Committee has played in this effort to conquer this dreaded disease. Thank you for permitting us to appear before you.

STATEMENT OF CHARLES A. LEMAISTRE, M.D., PRESIDENT, AMERICAN CANCER SOCIETY, AND PRESIDENT, M.D. ANDERSON HOSPITAL AND TUMOR INSTITUTE, UNIVERSITY OF TEXAS

Senator PROXMIRE. Our final witness is Charles A. Lemaistre, M.D., president, American Cancer Society, and president, M.D. Anderson Hospital and Tumor Institute, University of Texas.

Dr. LEMAISTRE. Thank you, Senator Proxmire.

I am Charles Lemaistre.

Senator PROXMIRE. I beg your pardon. I mispronounced your name.

Dr. LEMAISTRE. That is quite all right, sir. It is an old French name that has been highly Anglicized.

Senator PROXMIRE. I took 9 years of French in school, and I can't understand a word of it.

Dr. LEMAISTRE. And you I are together on that point.

I represent 2½ million volunteers in the world's largest volunteer health agency coalition. Each year, the American Cancer Society is privileged to come before you and present, in effect, a citizens budget. This is a reasoned judgment of what the society feels about that portion of our natural resources that is needed to sustain the rapid progress that has been made in the war against cancer.

PREPARED STATEMENT

I have submitted a detailed statement for the record with regard to support of the NCI budget.

Senator PROXMIRE. Without objection, that will be printed in the record in full.

[The statement follows:]

STATEMENT OF CHARLES A. LEMAISTRE

Mr. Chairman and members of the Committee, I am pleased to be here today to present the "Citizen's Cancer Budget" on behalf of the American Cancer Society, the World's largest voluntary health agency with over two and a half million active volunteers.

I am Dr. Charles A. LeMaistre. I am President of the American Cancer Society. In addition, I am President of the M.D. Anderson Hospital and Tumor Institute, which is part of The University of Texas System Cancer Center in Houston, Texas.

Mr. Chairman, each year the American Cancer Society recommends a "Citizen's Budget" figure for the National Cancer Institute to the Congress. Traditionally, this figure has represented the judgement of the Society regarding that portion of the national resources which the U.S. Government should dedicate to the battle against cancer. Also, traditionally, the Society's figure has been considerably higher than that recommended by the President in his annual Budget Message.

While the Society's recommendation has been higher, it has in every instance, represented the Society's attempt to be practical and responsible, while at the same time, cognizant of what funds are necessary to fight cancer.

The national economic situation required a scaling back in 1985. Last year, the Society's position was that while the need for a national investment in NCI of $1.5 billion was fully justified, the Society was recommending an appropriation of $1.3 billion, and asking the scientific community to roll up their sleeves, emphasize economies, do more with less, and make up the remaining $200 million in productivity gains, deferral of major purchases, and other means, to bring the total FY 1986 national investment in cancer research to $1.5 billion.

Congress responded by appropriating $1.258 billion -- nearly $100 million over the previous year, and almost to the ACS recommended figure of $1.3 billion. We especially applaud and commend this Committee, Mr. Chairman, and particularly your leadership, for appropriating that additional $100 million.

FY 1987 poses a fiscal problem more severe than any previously faced by the government. The federal deficit is higher than it has ever been. Congress, in an attempt to gain a measure of control over runaway deficits, passed the Gramm-Rudman-Hollings bill requiring a balanced budget by 1990; to be accomplished by deep, across-the-board budget cuts each year, from now until balance is reached.

With rare exception, no government program will be spared the effects of Gramm-Rudman-Hollings. The National Cancer Institute has already lost $54 million in the first round of Gramm-Rudman-Hollings budget cuts. Thus, the NCI budget for FY '86 has been reduced from the original $1.258 billion to $1.202 billion. This will result in numerous significant cuts in NCI's program including: loss of federal funding for five Comprehensive Cancer Centers and five organ site programs -- with marginal funding for the remaining centers and organ site programs; loss of some vital clinical cooperative groups; and severe cuts in the Cancer Communications Program, among others. Research grants could be reduced across-the-board. Severe loss of the momentum in progress against cancer through research, prevention, and treatment that is so vital to a dynamic program, will result.

Mr. Chairman, cancer does not recognize or acknowledge the problems that government has with its finances. Cancer knows no boundaries. It is apolitical. It will continue cutting its inexorable swathe through the lives and means of Americans regardless of Medicare cuts, defense appropriations, or Gramm-Rudman-Hollings.

With the American people, cancer is the top health priority. Every year the American people renew their expression of this priority through significant increases in their support of the American Cancer Society's programs of research, support, education, and service. The Society carries out its programs with no funds of any kind from government, and, because of this, is in a unique position among private sector organizations to speak with independence and objectivity on national cancer research and treatment support needs.

The American Cancer Society does not believe that the National Cancer Institute budget should be cut. The Society calls for increasing the NCI appropriation to $1.322 billion in fiscal year 1987. The American Cancer Society believes that the small, proposed increase would serve to maintain the level of momentum vital to assuring continued progress against this disease.

The dynamic progress against cancer cannot survive abrupt reductions, program cancellations, and across-the-board disruptions in personnel. Cancer has no respect for man's other problems, and continues to drain energies and resources of our nation and its people to the tune of approximately $40 billion a year in lost wages, jobs and medical costs.

But while our nation has great difficulty containing the annual $40 billion leak in our national economic dike that is represented by the cost of cancer, individuals and organizations like the American Cancer Society have to act responsibly. It is incumbent on us to do our part in sharing solutions, as well as responsibility for the cause of our current fiscal problems. For this reason, the Society is asking only for a minimal increase in the NCI appropriation, to "mark time", until the current fiscal crisis is relieved. We believe that the simple cost of living increase we recommend would serve to carry the National Cancer

Program through this crucial period in our nation's economic history.

We sincerely believe, Mr. Chairman, that the funds that this Committee has appropriated during the past 15 years to the National Cancer Institute, represent the most productive health and medical research investment our nation has ever made in terms of real returns for our citizens. In the short span of those few years, more progress has been made against cancer -- man's most complex and determined health and medical enemy -- than in all of previous history. You, and your committee have literally made history through the wisdom of your decisions about funding of cancer research.

I say this in the context of recommendations, which we believe to be unwise, which have been made to reduce the NCI appropriation for 1987. We do not minimize the importance of deficit reduction. However, in considering the appropriation for cancer research, we urge you to consider the tremendous fiscal consequences of disrupting the cancer program. As I stated earlier, cancer costs this nation $40 billion every year. That cost is a significant factor in the national deficit. It will not be reduced if we lessen our efforts in fighting cancer. On the contrary, we will reduce and eliminate the cost only by capitalizing on the breakthroughs made as a result of the investments in cancer research over the past fifteen years. Let me assure you, Mr. Chairman, that the breakthroughs that we are seeing now are historic. We can not afford to lose momentum now.

I would like to cite a few of these returns which have helped bring the number of lives saved from cancer from one in three, just a few years ago, to one in two today.

To really appreciate and understand the phenomenon of progress against cancer, it is important to accept the fact that cancer is a basic biological process. There are billions of cells in the human organism. Every one of them has a control mechanism dictating when it will divide, how frequently, when it will stop, or start division. At some point, for a variety of reasons: heredity, influence of carcinogens, lifestyle, environment, aging, some cells lose their ability to reproduce in their normal programmed way. This loss of control becomes cancer. Therefore, one might say that understanding cancer and its process is to understand life, and its process. It is a tall order, but significant inroads are being made. The genius of man is slowly, but decisively stripping away the mystery of those phenomena through research, and the fruits of that research are represented in the design of new ways to attack the disease, with increasing success.

Research is yielding vital knowledge of the basic biological process. Dr. DeVita described the most dramatic developments to you in his exciting testimony several weeks ago. I would like to reiterate some of the more important things he told you.

Based on new knowledge of cancer biology, major efforts are under way to prevent cancer; to reverse the cancer process by nudging a transformed cell back to normal; to employ the exquisite network of our immune system to defend against cancer; to refine treatment and destroy more selectively cancer cells; and to block metastasis -- the ability of cancer cells to spread and kill. The investment in basic research made possible by the National Cancer Program has led us today to an unprecedented understanding of the cancer cell.

As we know, chemotherapy kills cancer cells. Unfortunately, it often is a very unpleasant treatment for the cancer patient, because while killing cancer cells, it also subjects healthy cells to its damaging impact. Fortunately, the prospect for cure outweighs the trauma of the treatment in most people. One of the problems with this effective, but sometimes unpredictable form of treatment is resistance of the cancer cell to the chemotherapy. It has been learned that such resistance can be caused by exposure to some environmental toxins. A recent, and important advance is represented in a new conceptual unity that now connects such distant events as drug resistance in advanced cancers with the same fundamental mechanism of cancer transformation itself. It is now apparent that a common set of genes controls enzyme systems that resist the carcinogenic effects of environmental toxins and help prevent cancer in animals and humans. The ultimate failure of this process is followed by the loss of control of the switches that regulate growth, leading to malignancy. However, it is now known that cancer cells retain these defenses in some capacity and are able to resist the very chemicals used to treat them. Now this information can be used on a practical level since modification of these resistance genes could improve treatment with drugs with potentially startling simplicity.

While cancer cells exert lethal effects by growing out of control, they appear to be immature, somewhat confused cells, aberrantly using the same genetic mechanisms established for normal growth and development. New biology has allowed researchers to tap into this genetic machinery at the heart of the cell and find minute, but critical, differences in genes of normal and cancer cells. They discovered oncogenes involved in transforming healthy cells into cancer cells. The counterparts of these genes, proto-oncogenes, are involved in normal growth and development. It has long been thought that cancer is a multistage process with intricate circuits and switches, working at different points of disease progression and at different times. Some substances serve as initiators that start but cannot finish the cancer-causing process without the help of promoters. Most promoters cannot work in cells that have not been initiated.

With new technology, it is possible to study the genetic switches which trip the sequence of events that control growth and development or lead to cancer. Although cancer is over 100 different diseases, scientists feel certain they share some basic mechanisms that set off the disease. Understanding this has already led to the use of this data at the clinical level.

Reducing the incidence of cancer is one of our major goals. One of the best hopes for accomplishing this in our lifetime is controlling the effect of cancer "promoters" in people who are exposed to cancer "initiators". Real progress has been made in efforts to interfere with promotion. For example, curtailing wide use in the 1970's of the "promoter" estrogen used for menopausal symptoms, led to a dramatic, rapid reduction in uterine cancer. Cigarette smoke contains both initiators and promoters, but the removal of the promoters' effect may be the key event in avoiding lung cancer. This year NCI reported that the incidence of lung cancer in white men has decreased significantly for the first time in at least 50 years. This provides evidence that the exposure to chemical initiators in cigarette smoke does not irreversibly destine a person to develop cancer and that people can reduce their cancer risk by interrupting the carcinogenic process at its later stages by quitting smoking.

These are just a few of the exciting developments in understanding cancer that have come out as a result of the great support of this Committee to the National Cancer programs. I commend Dr. DeVita's exciting testimony to you for further elaboration.

I call particular attention to the new "apportionment" process imposed on the NCI and other NIH institutes. We believe that language should be included in the appropriation bills that would allow NCI, and other institutes, to apportion their reduced resources in the way that the leadership of these agencies believe is the best for their programs and their objectives.

Mr. Chairman, we at the American Cancer Society understand our Nation's fiscal dilemma. We do not envy your role in tiptoeing through the deficit reduction mine field on your way to allocating our limited national resources to real needs, such as the cancer program. But we do believe that you have the power and authority to prevent unwise applications of cost cutting measures.

Dr. LEMAISTRE. Thank you, sir. I would just like to take a few minutes to review some of the recent progress, that part my colleagues covered who have gone before, and also a few other points need to be crystal clear in the record.

Strides have been made possible through knowledge from biomedical research, as Grace Monaco just said, but that knowledge was gained since the passage of the landmark National Cancer Act in 1971. Let me be more specific about this. Many of those advances came about only because of the support of American scientists through the terms of that act.

Each of the dollars that have been invested by the Congress of the United States in the last 15 years, we have earned a dividend of enormous proportion and, in my opinion, perhaps the greatest yield in an investment in health research in the history of man.

You have to remember that cancer, however, is a formidible adversary. It has been with man as long as recorded history. Until just recently, cancer has dominated that relationship, but in the last two decades, things have changed, and they have changed dramatically because of the research support from the Congress of the United States.

We have learned more about cancer in those two decades than in all of the history of man. And the results are very clear as a result of this knowledge.

Senator PROXMIRE. Let me just interrupt to say that I think many of us are aware of that progress. However, I was not aware that this country, through Federal funding, has been that effective. Is that right? Do we outpace other countries?

Dr. LEMAISTRE. No question about it, Senator.

Senator PROXMIRE. Most of the successful research has been done by the United States?

Dr. LEMAISTRE. Yes; I don't think there is any question that the biomedical research mechanism in this country now is the most formidable one in the world.

Senator PROXMIRE. Has the United States been more successful than all other countries combined, would you say?

Dr. LEMAISTRE. I would not be able to measure that accurately, sir. I know in comparison to other individual countries, the statement is true.

But I think the fact that it has been transformed into very tangible results so that cancer is now a highly curable, chronic disease, the most curable of all chronic diseases, is pure testimony to what it means to the people of America.

If you look at the fact that nearly one-half of the once deadly cancers are now cured without qualifications, cured, then that is a remarkable achievement in itself. But we often not ought to overlook that the one-half that can't be cured are much better off. They have longer survival, and they have a higher quality of life for those patients. This is equally important.

Senator PROXMIRE. We are making progress in most of those areas. In the future, we might be able to add to that.

Dr. LEMAISTRE. I am certain of that. The American Cancer Society has listed 14 forms of cancer that formerly were deadly only two decades ago. Now each of those is largely curable.

Let me turn very quickly to say, to follow your point, our cup is about half full, and it is half empty. There are three major killers in lung cancer and breast cancer and colon cancer yet to be conquered. That is where the targets are being directed at this point in time.

In the past few years, we have learned a great deal more about the fundamental parts of the biomedical research effort, as it was related to you a moment ago. But we have got a long way to go in terms of completing this job, and it is our opinion that the American public places this at very high priority and wants to see this completed in an orderly and timely fashion.

Against this backdrop, I appear before you today on behalf of the American Cancer Society to assure an appropriation of $1,322 billion for fiscal year 1987. In our opinion, that is the level that is necessary to assuring the continued progress against cancer.

As you will recall, the bypass request was $1.5 billion, and in our opinion, looking at the cost-of-living increases and the others, just to maintain this, comes out to about $1.3 billion in order to maintain this remarkable machinery that is in place. I would also call your attention to the new apportionment process imposed on the National Institutes of Health.

Each of these Institutes needs a degree of flexibility. To provide that flexibility, we recommend that language be included in the appropriations bills to permit each Institute to apportion its own resources to best address these mandated goals.

The achievements of these past few years are but prologue to the even greater accomplishments that are on the horizon ahead of us. We have the team in place that has the determination and the momentum and the creativity, but they will need the dollar resources in order to complete the hard-fought battle against cancer.

I thank you for this opportunity to appear before you, and I would be very pleased to answer any questions.

Senator PROXMIRE. Doctor, you mentioned that the No. 1 cancer was lung cancer.

Dr. LEMAISTRE. That was deliberate. The reason for that, Senator, is that we have not made much progress in lung cancer. Lung cancer is a very deadly disease. It is caused by cigarette smoking.

Senator PROXMIRE. I was going to say that the progress we are going to make will be made in large part by prevention, stopping cigarette smoking.

Dr. LEMAISTRE. Stopping the taking up of the habit as the Surgeon General concurred and the American heart so we have a smoke-free young America by the year 2000, doing all we can to help those who are addicted. There is no reason to skirt around that. The addiction to nicotine is about five to seven times as great as the addiction to alcohol.

Senator PROXMIRE. What is the incidence of lung cancer among those who smoke compared to those who do not smoke?

Dr. LEMAISTRE. If you take all the data on men and women, and these data are 18 months old, as I recall, about 83 percent of the lung cancer that occurs in Americans occurs in cigarette smokers. As you know, we have, in recent studies, identified that passive smoking, breathing somebody else's cigarette smoke, doubles the risk of developing lung cancer.

So there is yet another contributor.

Senator PROXMIRE. So passive smoking doubles the risk. But if you have a reasonably heavy smoker, say, two packs a day or something of that kind, compared to somebody who doesn't smoke at all, the comparative incidence of lung cancer would be what, 10 to 1?

Dr. LEMAISTRE. Just about. Those are the lowest ratio figures. There are some that calculate up, that the Russian roulette odds are somewhere around 1 to 10 and some as high as 10, 12, 13. It is in that range, yes, sir.

Senator PROXMIRE. That is very, very impressive. Again, I think this is a great, great, cause. You say this is the one area where we are not making progress except by dissuading people from becoming addicted?

Dr. LEMAISTRE. Let me clarify the point: I believe we have done less to change the outlook for the cigarette smoker who goes onto develop cancer after a decade, decade and a half of smoking than in any of the other diseases in treatment.

On the other hand, Senator, you will recall that in 1964, we presented the Surgeon General's Advisory Committee on Smoking and Health, and 18 million American men quit smoking in 1965. Then the Congress has done a number of other things with the Labeling Act that has called attention to the public, to this danger.

Only this year have we seen the results of that, giving up of smoking and decrease in the taking up of the habit, by which now, we would estimate, is about 21 percent of the American female and about 27 percent of the American male down from 52 percent of the American males in 1965. So there has been a tremendous change in the taking up of the habit.

Senator PROXMIRE. But there has been less progress among women than among men?

Dr. LEMAISTRE. Well, women, Senator, took up the disastrous experiment that men engaged in 20 years earlier in taking up the cigarette smoking habit. Now, in 17 of our States, lung cancer is more common in women than breast cancer. We predict that within the next few years, that will be the most deadly cancer in women. It is clearly the most difficult one to treat, and you are absolutely right: We ought to be emphasizing that we do everything that we can to prevent the taking up of the habit and to do away with the misleading advertising that seduces young people into believing that this will cause them to be healthy or successful or sexy or any of those misguided ads that you and I see in the papers every day.

Senator PROXMIRE. I think one of the most effective dissuaders would be if it can be shown, actually, that cigarette smoking causes wrinkles. I think that more women——

[Laughter.]

Senator PROXMIRE [continuing]. Will desist from smoking if they think it is going to make them unattractive than if it is going to save their lives.

Dr. LEMAISTRE. Senator, you and I agree on that. There is a plastic surgeon in New York who has published on that point. He does claim that it advances the wrinkle factor by about 10 years in women. If that research can be substantiated and become more knowledgeable to young ladies, I think we have got the answer.

Senator PROXMIRE. One more question. I understand that studies show that environmental cancers, asbestosis, for example, are made much worse by smoking?

Dr. LEMAISTRE. Yes; the individual risk with asbestos would be about a fourfold increase, and with cigarettes, about a tenfold to elevenfold increase. Put them together and you get a synergistic effect of a 44 times increase. So it is deadly in combination. The carcinogenic effect is the thing that is so deadly. That has been well defined over the last 30 years.

Senator PROXMIRE. Thank you, Dr. Lemaistre, thank you very, very much for your fine presentation.

SUBCOMMITTEE RECESS

The subcommittee will stand in recess until Tuesday, when we will hear from witnesses on the budgets of the National Heart, Lung, and Blood Institute, the National Institute of Arthritis, Musculoskeletal, and Skin Diseases, the National Institute of Diabetes, Digestive, and Kidney Diseases, and the Library of Medicine.

The subcommittee stands in recess.

[Whereupon, at 12:25 p.m., Thursday, April 24, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, April 29.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

TUESDAY, APRIL 29, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Hatfield, Specter, Proxmire, and Inouye.

NONDEPARTMENTAL WITNESSES

STATEMENT OF ROBERTA DeVITO, PRESIDENT, AMERICAN BRITTLE BONE SOCIETY

ACCOMPANIED BY:
CONJE DeVITO
ANNA MARIE DeVITO

Senator WEICKER. Do you know what I am holding in my hand?

Senator INOUYE. Is it a credit card?

Senator WEICKER. It is an identification card that says: "Conje DeVito, Candidate for President in 2012." [Laughter.]

I think we all agree with that, Conje.

Conje DEVITO. If you want to run for President, I will be sure to support you, too. [Laughter.]

Senator WEICKER. Conje, you are the only person I know who feels that way, certainly nobody in my own party. [Laughter.]

It is great to have Conje and Roberta back with us on behalf of the American Brittle Bone Society.

Conje, what is your sister's name again?

Conje DEVITO. Anna Marie.

Senator WEICKER. Anna Marie, every year, you get prettier and prettier. It is just great having you here. Nice to have you all.

Please proceed.

Mrs. DEVITO. Thank you very much.

For the record, I would just like to submit the written testimony so that it may be published in its entirety in the record, and just to speak extemporaneously for just a moment, to let you know that, naturally, as your children get a little bit older, they take a larger role in the proceedings. So, actually, except for a few very brief comments, I think I will turn the meeting over to Conje. He can say it better than I can, and certainly, because of you folks, he has had better results than I think I could have ever had because he speaks right from personal experience.

The thing that I want to say, and thank you for right now, is the establishment of the new institute at NIH, the National Institute for Arthritis, Musculoskeletal, and Skin Diseases. Naturally, brittle bone disease falls within the realm of the musculoskeletal.

We are looking for, with this new institute, increased focus in the area, and we are hoping that the funds can come through that will see the new institute become viable as quickly as possible.

Naturally, we are concerned with the new institute starting up, but you do have to make some sacrifices in all program areas. We are willing, if not too anxious, but we are willing to do what is necessary on behalf of the good of all, of the programs that will be served by that institute to take as much of a cut as we have to.

This year, the NIH projects a budget for osteogenesis imperfecta [OI] research of $4,259,000. I don't know how much that figure impacts on people who are used to speaking in terms of many, many millions more than that, and even billions, but when we first started testifying here in 1978, and it is to the credit of this committee that the increase has been so dramatic, osteogenesis imperfecta was getting in the neighborhood of $70,000. This is wonderful, and I applaud you for that sincerely from the bottom of my heart, the reason being sitting right here.

Whatever we can get of that NIH projected budget, we would appreciate it.

The osteoporosis budget is scheduled this year at $5,488,000. This is an area that does not affect me personally, and I hope it never does, but it does affect many, many women. One in four women sitting in this room will get osteoporosis. That is a figure that is quite below, probably, what it needs at this point in time, and it will probably be the lowest figure that you will ever see for osteoporosis. There are probably about 20 million women right now by NIH figures suffering from brittle bone.

Suffice it to say that whatever can be gotten in the way of an increase there would be much appreciated.

At this point in time, I would like to turn to Conje so that he can give you his closing remarks.

Senator WEICKER. Conje.

Conje DEVITO. Senator Weicker, and members of the committee: I would like to say how much I enjoy the opportunity to be here presenting testimony before this committee. I, also, am probably getting some good experience on the way to the day I get to sit in one of your chairs some day. [General laughter.]

Getting serious, the older I get, the more I recognize how important a job I have because I know that I represent a lot more people than just me. I know they are depending on me.

I am taking my appearance here a lot more seriously as you are listening to me and acting on my request of more funding of my brittle bone disease and for osteoporosis, too. For this, I would like to thank you for showing how much you are concerned about me.

Each year, this committee has taken a leading role to see that there is growth in funding for research. Now, in fiscal year 1987, the NIH projects a budget of $4,259,000 for OI research, and I am asking that you make sure that this amount does not get cut when you mark up the budget.

I really feel that you will keep me in mind when you get down to the hard work of preparing the budget, and I hope that you can convince the Congress that the money they spend on OI is worth it because I am worth it.

Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you. We will insert your statement in the record in its entirety at this point.

[The statement follows:]

STATEMENT OF ROBERTA DEVITO

In support of the concensus of the Coalition of Organizations concerned with the programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, I suggest funding that is felt to be necessary to maintain research efforts at current service levels.

1. One hundred million dollars for investigator-initiated research grants (RO-1). This support level would fund 223 new grants in FY 1987, and a total of 612 new and continuation grants. At this level, the estimated award rate for new grants would be 34%, with a priority score payline of 170. The $100 million we urge is only 3% greater than the current services level.

2. Funding at current levels for training and contracts. Except, an increase of $2.4 million over current services in Centers funding to support 6 core centers in dermatology. I especially urge initial funding of Specialized Centers of Research (SCORs) to target multidisciplinary research approaches in three areas: osteoporosis, osteoarthritis, and rheumatoid arthritis, as both the House and Senate Appropriations Committee's recommended last year.

3. Reasonable funding of the category which includes Clinical Investigator and Physicican Scientist awards. Both must have emphasis if our research community is to remain viable in future years. No new awards would be possible under the President's FY 1987 budget.

4. Intramural research must be strengthened to complement extramural activity.

5. NIH projects for FY 1987 a budget of $4,259,000 for osteogenesis imperfecta and of $5,488,000 for osteoporosis. I recommend that this service level be supported. Except, an increase in funding of osteoporosis research that is commensurate with the seriousness and widespread suffering caused by this aberration of bone metabolism.

6. Another $1.5 million for NIAMS staff over and above the additional $1 in the President's FY 1987 budget. Under the NIH organization plan for NIAMS, 57 staff members have been slotted for NIAMS. At these personnel levels NIAMS cannot function as an independent Institute. NIAMS requires another 36 personnel.

If $1 million is added for this purpose as is in the President's FY 1987 budget, this will permit the placement of 15 to 20 staff.

Another $1.5 million is necessary to provide the minimum of 36 additional personnel.

More than 50 million Americans are affected by arthritis, musculoskeletal and skin diseases. Of these, twenty million have osteoporosis at an annual cost to society of $6 billion. Many thousands more suffer a systemic syndrome known as osteogenesis imperfecta.

Biomedical research, and more specifically, research to improve the lives of these people should be one of the highest of this nation's priorities.

All of these serious diseases or conditions result in morbidity, mortality and disability, which cost the American economy many billions of dollars each year in medical care, lost wages and productivity, lost taxes, increased disability and workers' compensation payments, and increased social services costs.

Research advances in the past decade have brought about improved treatment, control of disease, better diagnostic methods, and important new surgical procedures which strongly indicate that accelerated and targeted research efforts can sharply ameliorate, control, prevent, and cure a number of these diseases. This promise for the future was a major reason for the creation of the new Institute.

The members of this Subcommittee are aware that NIAMS was established in law on November 20, 1985. Fiscal Year 1987 marks the first opportunity for Congress to address research needs of the programs encompassed by this new Institute as a separate budget line item.

The President has supported the creation of NIAMS, and the Congress has endorsed it through several nearly-unanimous votes. I now urge you to appropriate funds for the Institute (as outlined in the Summary of Recommendations) at a level adequate to allow NIAMS to initiate the focussed, national research program contemplated by Congress at the time of its establishment.

Conclusion

The Coalition of Organizations, which I support, believes that the amounts it is recommending for FY 1987 are fiscally sound and minimally adequate to make NIAMS operational and effective as an NIH research institute.

There is ample scientific justification for the FY 1987 budget proposed. The loss of momentum in biomedical research through reduced or level funding would mean a serious loss of research opportunity for many years to come and the real potential exists for the loss of an entire generation of investigators.

We urge Congress to enact, and the President to approve, appropriations for FY 1987 at the level the Coalition recommends, as the minimum necessary to firmly establish NIAMS and to begin the level of research effort essential to finding the answers to the diseases addressed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Senator WEICKER. Listen, I will tell you, do you know what you ought to do in this room, you ought to hire this young man to present your case before the committee. I think that you can clear out the room, and all your requests will be granted.

Conje, you are a very eloquent young man. I have no doubt that you are going to be sitting in this chair, and even that chair.

Let me ask you or your Mom, in your contacts with the National Institutes of Health, have they actually started the program going; are they just in the startup stage; where do things sit?

I did not ask this of the doctors when they were here.

Mrs. DEVITO. They are in the startup stage of getting in the staff. Apparently, there is a lot more staff needed, not to open up a new can of worms, I try to avoid that, but apparently a lot more money is needed to add the staff that is necessary to make the budget viable, and this is something that the coalition of organizations concerned with that Institute is probably going to be asking for. It is in my statement.

Yes; they are in the process of looking for a director for that Institute. There seems to be quite a working arrangement between the Institute that we are pulling our nucleus from and the new Institute, so there is quite an interaction at this point.

Senator WEICKER. Senator Inouye.

Senator INOUYE. All I can say is that if you are ready for a motion, I am ready to make it. [Laughter.]

Mrs. DEVITO. Thank you for your support.

Senator WEICKER. In other words, he wants to grant your request, Conje.

Conje DEVITO. Thank you very much.

Senator WEICKER. I think that we will certainly keep a very special eye on this. I suppose the part of your statement I like the best is where you say that you are speaking for a lot of other people. I think that that is a very important thing throughout life, and you are a fine person. You just keep going the way you are going.

Conje DEVITO. Thank you.

Senator WEICKER. Anna Marie, you keep getting prettier every day; all right?

There are a lot of women, and we need women, as a matter of fact, in the U.S. Senate, so you think about it, too.

Mrs. DEVITO. Conje has deigned to say that she could be his vice president. [Laughter.]

Senator WEICKER. That is good.

Thank you very much.

Mrs. DEVITO. Thank you very much.

STATEMENT OF LUCI BAINES JOHNSON ON BEHALF OF AMERICAN NURSES ASSOCIATION, NATIONAL LEAGUE FOR NURSING, AMERICAN ORGANIZATION OF NURSE EXECUTIVES, AMERICAN ASSOCIATION OF COLLEGES OF NURSING (CANADA)

Senator WEICKER. Our next witness is Luci Baines Johnson, representing the American Nurses Association, and the National League for Nursing, the American Organization of Nurse Executives, and the American Association of Colleges of Nursing.

Senator Inouye.

Senator INOUYE. Mr. Chairman, I have had the privilege of knowing Ms. Johnson for many years. She has had a 20-year career working in health and education. Her interest in health and education has manifested itself in the formation of a visual screening program for Project Head Start.

She has been chairman of the American Heart Association for fund raising in Texas. She is the first female member of the Seton Medical Center Advisory Board. She has been a lecturer in the field of visually related learning, and she presently serves as a member of the Boston University Medical School Advisory Board.

Throughout these years of voluntary work, she has maintained a deep commitment to nursing, and the advancement of professional nursing. Her interest in nursing began as a nursing student in 1965 in Georgetown. Since then she has served as chairman of the University of Texas System of Schools of Nursing, chairman of the University of Texas School of Nursing in Austin, as a member of the National League of Nursing Board of Review and Executive Committee.

She has been honored with awards of distinction by the University of Texas School of Nursing at Austin, the Texas Nursing Association. She is presently a working mother of four children, and an officer of the Parent and Teacher Association.

I am pleased to present Ms. Luci Baines Johnson.

Senator WEICKER. It is a pleasure to have you with us.

Ms. JOHNSON. Thank you very much.

The honorable Senator from the Great State of Hawaii has honored me in sharing the credentials that I bring to you today, Senator Weicker, and I thank him.

Over the past 20 years, I have seen too much, heard too much, read too much to remain silent about nursing education and research. Federally funded programs supporting nursing education and research work. They work for nurses, but they benefit everybody. Their preventative nature reduces fiscal and moral costs.

Our country has tough choices. We have limited resources, and unlimited requests. You, Mr. Chairman, and your colleagues are in the painful position of having to choose which programs our Nation can afford. I am here to ask for your continued support of nursing education and research because it happily makes economic as well as moral sense. Good sense morally because greater education of nurses results in greater public access to greater numbers of people. For example, Federal funding of advanced education in nursing has prepared nurse practitioners to work as independent care providers in HMO's, hospices, home and community settings, as well as in hospitals. Good sense economically because increased access and continuity of health care, the highly educated nurse practitioners provide results in lower costs. It simply costs less dollars to prevent serious illnesses than it does to cure them.

Research in nursing has also reduced costs by providing new nursing interventions that have decreased pain and suffering, and financial burdens, but demand continues to outstrip supply, and needs are increasing.

The prospective payment system [PPS] has created an immense demand for nurses with advanced degrees to work in community care settings, to coordinate home care for patients released from hospitals.

Recent directives to cut funding for nursing education and research have been justified on the basis of an oversupply of health care providers, and the need to curb the Federal deficit. It is true that there is an oversupply within some health care professions, but it is not true for nurses with advanced degrees. In fact, several Federal studies show the exact opposite, a serious and continuing shortage of nurses with advanced degrees in clinical specialties, administration, and research.

Reduced funding for advanced degrees in nursing means decreased access to health care for the aged, the indigent, and the young. To show you the importance of access to care that advanced degree nurses provide, let me focus on just one area of great national need, that of reducing the rate of infant mortality.

Currently, the United States has an infant mortality rate of 11.7 deaths per 1,000 live births, which ranks as 17th in the world. A 1985 research study reveals that since 1978, the infant mortality rate has actually increased in 11 States. Instead of improving with time, the picture has worsened. Decreased access to health services is a major factor contributing to this increase in infant mortality.

In Chicago, an adolescent family center, staffed by nurse clinicians and nurse midwives, has dramatically decreased infant mortality rates. This clinic's patients are in the qroup at greatest risk for infant mortality, they are Black, less than 15 years of age, poor, and single, yet the rate of infant mortality in the center is approximately one-third lower than the rate for the entire rest of the city of Chicago. The difference—access to nursing care.

Too often, mothers of such a high risk group give birth with no prenatal care because expense prevented their access to medical care, yet access to catastrophic care is readily available in our neonatal units which are unequalled in other nations.

Preventative nursing care reduces catastrophic illness and its catastrophic costs, doesn't it make sense, both financially as well as morally, to provide preventive nursing care?

Research in maternal and child health care has also proven to make moral and financial sense. For example, a team of nurses recently completed a study which identified nursing intervention that would hasten the neurological development of premature babies, allowing them to gain weight more quickly, and leave the hospital approximately 4 days sooner. This is only one of countless examples of how nursing research provides practical, preventive progress for our problems.

As much as I recognize our Nation's need to tighten its fiscal belt, I believe that there is evidence to justify that reducing funds for programs in nursing research and advanced nursing education is false economy. It is being simply penny-wise and pound-foolish.

This committee's support of advanced education has improved access to prenatal care. Your support of research has resulted in reducing costs and improving quality of care. Mr. Chairman, I am here to request your continued support of nursing education and research by joining us in opposition to the administration's proposed massive cuts on both fiscal and moral grounds.

Benjamin Disraeli once said: "The health of the people is really the foundation upon which all of their happiness and all of their powers as a state depend." For the health of our people, we respectfully ask this committee to continue to support nursing education programs and the National Center for Nursing Research at the National Institutes of Health.

Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. Your statement will be placed in the record.

[The statement follows:]

STATEMENT OF LUCI BAINES JOHNSON

Mr. Chairman, I am Luci Baines Johnson, and I appear before you today on behalf of the American Association of Colleges of Nursing, representing 382 colleges and university schools of nursing; the American Nurses' Association, representing 188,000 nurses throughout 53 constituent state nurses' associations; the National League for Nursing, comprising 1800 institutions and 15,000 individual members; and the American Organization of Nurse Executives, representing over 2500 nursing service administrators.

I come before you today as an interested citizen who has worked for the advancement of professional nursing over a twenty year period. My committment to professional nursing began in my early days as a nursing student at Georgetown University. I continued this commitment to the advancement of nursing through service as the Chairman of the University of Texas System School of Nursing Advisory Board and as a member of the National League for Nursing Board of Review and Executive Committee. It is because of this interest in nursing that I come before you to request your support of continued funding for advanced nursing education and research.

There have been great changes in the health care system over the last few decades. One of the most profound has been the emergence of nurses with advanced degrees as independent care providers in hospitals, HMOs, hospices, and home and community care settings. As technologies for health care have become more complex, and as needs for complex care and long term care have grown in our society, the role of the nurse has become increasingly important.

Recent directives to cut funding for nursing education and research have been justified on the basis of an oversupply of health care providers, and the need to cut the federal budget deficit. It is true that an oversupply exists in some health professions. But it is not true for nursing. In fact, the opposite is the case. There is immense demand, for example, for nurses to work in community care settings to coordinate home care for patients released from hospitals. There is also a tremendous shortage of advanced nurse clinicians and nurse researchers.

In 1983, the Institute of Medicine (IOM) reported that serious and continuing shortages existed in nurses with advanced nursing degrees in clinical specialties, administration or research. In the *Fourth Report to the Congress on the Status of Health Personnel*, 1984, the Department of Health and Human Services projected that by the year 2000, the need for nurses with master's and doctoral degrees will be 400,000. At present only 200,000 nurses have this preparation. A 1985 Institute of Medicine Report, *Personnel Needs and Training for Biomedical and Behavioral Research* supports earlier findings of the Institute that a shortage of nurse researchers continues. This latest report calls for continued and increased federal support of nursing research.

As caring citizens, nurses are acutely aware of our nation's need to tighten its fiscal belt. Reduced funds for programs in nursing research and advanced education for nurses is false economy whose consequences will decrease access to health care for our aged, indigent and young. Previously, we have presented testimony regarding the importance of support for nursing education and research as this relates to gerontological health care. This year, we have chosen to focus on another area of national need, that of reducing the rate of infant mortality.

Currently, the U.S. has an infant mortality rate of 11.7 deaths per 1000 live births, ranking 17th in the world. Further, a 1985 report from the University of North Carolina cites that, since 1978, the infant mortality rate has increased among all infants in eleven states. The mortality rate for non-white infants has increased in 13 states including Maryland, Illinois, New Jersey, and North Carolina. White infant mortality rates have increased in nine states, among them New Jersey, New York, and Washington. Decreased access to health services and lack of public knowledge regarding the problem are two reasons for the worsening infant mortality picture. Those of us who are concerned for nursing and for the needs of the children of our society recognize that maternal-child health and infant mortality can be improved through access to nursing care. Advanced nurse clinicians such as nurse practitioners, nurse midwives and maternal child health clinical specialists provide cost-effective pre- and post-natal care. Therefore, it is imperative that an adequate supply of highly educated nurse clinicians and nurse researchers are available to improve access to essential pre- and post-natal care and to continue research on nursing interventions which can decrease infant mortality.

Nursing has long engaged in research and practice for the improvement of maternal-child health care. In the state of Oregon, two nurses, who are specialists in nurse midwifery and family nursing, recognized the acute need for increased pre- and post- natal care. These nurses, Mary Ann Curry and Carol Howe, worked with other nurses in the state to gather data which identified the need for improved access to maternal-child health care. They found that approximately 24% of all pregnant women in their study planned to arrive at the emergency room in labor, and that half of these would not have received any care during their pregnancy. These nurses were able to mobilize the financial resources of the state and the communities to improve access to care, especially for single pregnant women.

In Chicago, an Adolescent Family Center at Rush Presbyterian St. Lukes Medical Center, which is staffed by nurse clinicians and nurse midwives, has shown outstanding success at decreasing infant mortality rates for the patients served there. This is especially significant since the usual patient at this clinic is black, less than 15 years of age, poor and single. Such a group is at greatest risk for high infant mortality rates. Yet, the rate for infant mortality in this Chicago clinic was two-thirds the rate for the entire city of Chicago. This is an outstanding result of nursing intervention for maternal child health.

Nursing research has also been directed towards improvement of care for infants and children. One nursing research study identified nursing interventions which could hasten the neurologic development of premature infants, Infants exposed to these nursing interventions gained weight faster and left the hospital an average of four days sooner, resulting in tremendous cost savings to the health care system.

Funding for nursing education has been instrumental in providing support for the advanced nursing student, including the nurse midwife or the maternal-child health clinical specialist. For instance, the University of Connecticut, at Storrs, receives support through the professional nurse traineeship program which provides tuition and stipend help to the advanced nursing student receiving a master's degree in maternal-child health. In Kentucky, the Frontier School of Midwifery receives funding from the Advanced Nurse Education program to support faculty in the Family Nurse Midwife practitioner program. The University of Wisconsin School of Nursing also receives funding through this program for its maternal-child health and nurse midwife master's degree programs. The University of Florida School of Nursing receives advanced nurse education funding for the preparation of neonatal nurse clinicians and nurse midwives.

Decreased federal support of nursing education will have a devastating impact on the preparation of nurses with advanced degrees and result in fewer health care practitioners who are qualified to provide the highly complex care needed in today's society. Enrollments decline as these students cannot cover the cost of education on their own. Very often these students opt for part-time studies or no advanced nurse education when professional nurse traineeship support is not available. Increased numbers of part-time students also decreases curriculum continuity as predictions of student enrollment are difficuit to achieve and as the student's educational experience is extended. Advanced nurse clinicians and researchers are urgently needed today. Lack of federal funding for advanced nurse education would result in fewer students obtaining advanced nursing degrees and many of those would be part-time students who would therefore be delayed in entering the work force.

In addition to support for advanced nursing education, this committee's unwavering support fostered research on interventions to improve nursing care. Many of the research grants, in fact, focus on maternal child health care. One nurse researcher at the University of Illinois is receiving support for her study of the effects of early discharge from the hospital on low income mothers. Another nurse researcher at the University of North Carolina, Chapel Hill, is studying the effects of the neonatal intensive care unit on the parent-child relationship. A University of Maryland nurse researcher is also receiving support for her study of the adolescent's ability to cope with motherhood and her mothering skills. All of these research projects help to improve the health status of children. However they are threatened by the Administration's intent to cut funding for nursing research.

Previous support by this committee for nursing education and research has been a tremendous success. Continuation of this support will assure that nurses with advanced degrees will engage in nursing practice and research to meet the health care needs of a variety of patients. The support of maternal-child health education and research which this committee has provided has already shown outstanding results. Continuation of this support is essential to meet increasing demands for access to care and to combat rising infant mortality rates.

We must again request the opposition of this committee to the Administration's proposed massive cuts in nursing education and research programs. Mr. Chairman, it is obvious that federal involvement in nursing education has been an overwhelming success and needs to be continued. We again, therefore, respectfully ask the committee to continue to support the following nursing educational programs:

1. Advanced nurse education support which provides institutional support,
2. Professional nurse traineeships which provide the graduate student with tuition and stipend support to continue advanced nursing education,
3. Nurse practitioner program support which assists the development of programs for the education of nurse practitioners who work in schools, community health clinics and midwifery clinics, and
4. Special projects which provide grants and contracts to develop innovative approaches for improving the quality and availability of nursing care, and
5. Demonstration projects which provide grants and contracts to demonstrate improved methods for expanding access to nursing practice arrangements in the community and to encourage geographic and specialty distribution of nursing personnel.

In addition, we thank the committee for its previous support of the National Center for Nursing Research at the National Institutes of Health and urge continued funding for administrative support for the Center as well as the research projects so that the Center may achieve the goals for which it was created. Mr. Chairman, we gratefully acknowledge the committee's recognition of the continued need for federal funding for nursing education and research programs. We ask for your continued support of these nursing programs at sufficient funding levels to maintain current services. Thank you.

Senator WEICKER. Senator Inouye.

Senator INOUYE. Mr. Chairman, I would just like to note that their chairman and I have been working on this matter for quite some time. It has always haunted us that in this Nation, we spend approximately 50 cents per person for preventative medicine, while spending $1,440 per person for curing medicine. We know that for every penny applied, we are saving millions. So we are on your side.

Ms. JOHNSON. We thank you very much. I think that this is one of the special joys of this particular effort, it is that it makes sense, both economically and just in terms of basic human decency. We appreciate very much the opportunity to have spoken with you.

Senator WEICKER. I am very impressed with your testimony. I can assure you of another thing. You have no greater friend than Senator Inouye on this particular subject. It is always a great pleasure for the chairman when some member of the committee will take over in a particular area and make it his responsibility. Senator Inouye, in the area of nursing, has been the good shepherd as far as requests are concerned.

Ms. JOHNSON. Ever since I began to work with him.

Senator INOUYE. I would like to announce last week, I was made an honorary nurse. [Laughter.]

Senator WEICKER. When my time comes, given the choice of you or Lucy, you are going to find out just which one I choose. [Laughter.]

Ms. JOHNSON. Senator Weicker, we thank you very much.

Senator WEICKER. I might add that you also have some in-family support since my sister, Mary Audrey, is a nurse, and operates with the Hospice of the Valley out in Phoenix. What I don't hear from Senator Inouye, I hear when I get home.

Ms. JOHNSON. As you see, Senator, I also have a wonderful in-family with me, the coalition of nursing interests that have joined together and produced a very impressive document that we have submitted for the subcommittee's consideration. It is one that is really quite remarkable, the nurses from all walks of life and interests, who are most concerned and united in their interest in maintaining the opportunities for research in this country, and helping nursing help the American public.

Senator WEICKER. Thank you all.

STATEMENT OF VIVIAN GIORDANO, MEMBER, THALASSEMIA ACTION GROUP, COOLEY'S ANEMIA FOUNDATION

ACCOMPANIED BY MICHAEL DePHILIPO, NATIONAL EXECUTIVE DIRECTOR

Senator WEICKER. Our next witnesses, Vivian Giordano and Ralph Cazzetta, are members of the Thalassemia Action Group, Cooley's Anemia Foundation.

Ms. GIORDANO. I would like to introduce myself and Michael DePhilipo, and to tell you that Ralph Cazzetta could not be here today. He is a patient, as well as I am, and he was in a lot of pain today and had to go for his transfusion, so he could not make it.

Senator WEICKER. So who do we have here with you?

Ms. GIORDANO. This is Michael DePhilipo, the national executive director for Cooley's anemia.

I would like to begin.

Senator WEICKER. You go right ahead.

Ms. GIORDANO. I would like to say that the young gentleman who sat here for the first testimony and I have a lot in common. We don't just speak for ourselves, we speak for many other patients as well, and we speak from our hearts. I was very impressed with his testimony.

I just wanted to explain about the Thalassemia Action Group [TAG] because it does have something to do with that gentleman and myself. We began TAG because of your generosity and your help, and research has allowed us to live a longer life. The life span when I was born was only possibly 12 or 13. I am now going on 26, and that is only due to the money for the research.

Now that our patients are getting older, they are facing adult problems, and they have no one to turn to. So I began TAG, which is a support group for adult patients, 13 and older.

The Cooley's Anemia Foundation has the following suggestions for the appropriations for research and patient care in regard to Cooley's anemia:

That the Cooley's anemia research, treatment and care programs now underway in New England and New York, under the 15 percent set-aside of the Maternal and Child Health Program, for programs of regional and national significance be continued through fiscal year 1987. Bill report language has appeared in the appropriations bills in the House and Senate in the last several years, and that has maintained the program.

That considerable study be made of the impact of removing funding from the NHLBI and NIDDK for AIDS research.

We recognize the serious nature of this public health problem, but note that Cooley's anemia patients are also at risk, subject as they are to continuous transfusions.

We also believe, however, that the AIDS funding has been taken from ongoing blood disease research programs, and has weakened them, and prevented new initiatives, particularly in the area of blood transfusion, and the development of drugs to deal with Cooley's anemia and other anemias.

Additionally, it is becoming clear that the enormously important work being done in the NHLBI and NIDDK intramural programs on bone marrow transplants and drug development is threatened—we understand that there is the potential that an intramural laboratory in the NHLBI, which has chiefly been responsible for the work in Cooley's anemia research is now being threatened with fund withdrawal, and perhaps even defunding. This would be a major blow to those of us concerned with Cooley's anemia.

We support the ad hoc coalition's request for funding levels of $6.07 billion for the NIH.

We further suggest that the so-called sequestration process whereby deep cuts across-the-board in every program and subprogram, including the intramural research program, has already harmed research in Cooley's anemia and its associated basic biomedical research. If additional cuts like those projected of an additional 10 percent or more for fiscal year 1987 do occur, we believe that some research teams which have taken years to develop will disintegrate and our field of research will be set back years.

PREPARED STATEMENT

We, therefore, urge some system of action that will prevent Gramm-Rudman-Hollings cuts for fiscal year 1987.

Thank you.

[The statement follows:]

STATEMENT OF VIVIAN GIORDANO

Mr. Chairman, thank you for permitting us to testify regarding appropriations for research and care in Cooley's Anemia. I am Vivian Giordano, and with me is Ralph Cazzetta; both of us are members of the Thalassemia Action Group, a network of thalassemia patients 13 years old and over who felt the need to join together. I am also a member of the Legislative Committee of the Board of Directors of the Cooley's Anemia Foundation.

Allow me to give you some background about the Cooley's Anemia Foundation. The Foundation was founded over 27 years ago by a group of volunteers whose families had been stricken by Cooley's Anemia, named after Dr. Denton Cooley who discovered the disease, a fatal genetic blood disorder.

Thus, on September 20, 1954, the original core of volunteers officially incorporated the Cooley's Anemia Foundation in the State of New York as a national voluntary health agency for the express purpose of coordinating national and regional research activities, educating and counseling the public at risk (an estimated 20 million carriers of the genetic disease exist in the United States), providing patient care and family support services for those stricken with the disease, and also establishing professional education programs to provide the medical profession with forums in which to objectively share information about the disease and its treatment.

Cooley's Anemia, as indicated above, is a fatal blood disease that is passed from parent to child. It normally strikes children of Mediterranean-American parents including those of Italian and Greek descent, as well as Syrian, Israeli, and other population groups, including those from Asia.

For your information, we have attached to this testimony a brochure which was requested specifically by this Committee several years ago from the Department of Health and Human Services, which has been used widely throughout the United States, largely disseminated through out chapter network, to inform people not only about the disease, but about carriers of the disease. As you can see, the brochure stresses prevention through understanding.

We are extremely grateful to this Committee for the large amount of support that you have given to us over the past nine years that we have testified before your Committee.

We would like to express at this time several serious concerns that we have, which inpinge directly upon Cooley's Anemia patients and carriers.

First, we urge you to develop bill report language or some other mechanism by which the Maternal and Child Health Administration would be urged to continue those programs now existing in New England and in New York for the research and care of Cooley's Anemia patients. This program was established four years ago, has been on-going, and has been very successful. The Maternal and Child Health Administration of the Health and Human Services Department has been very supportive of this program, which is funded under the 15% set-aside for programs of national and regional significance.

Second, we wish to express our deep concern about the cuts that have been proposed by the Administration for fiscal year 1987, especially as to research. Specifically, we are concerned with the proposed cuts for the National Institutes of Health, which would cause the budget for the NIH to fall substantially below that for fiscal years 1985 and 1986.

We would like to refer to two institutes in this regard, the National Heart, Lung and Blood Institute and the National Institute of Diabetes and Digestive and Kidney Diseases.

In regard to the National Heart, Lung and Blood Institute, we wish to express our concern that many of the programs in hematology, which bear directly on Cooley's Anemia, will be suffering if the Administration's proposed fiscal year 1987 levels are agreed to. For example, we are very concerned about the intramural research program, which has been extremely successful in developing work on animal models (the rhesus monkey) for trials of bone marrow transplants and the use of drugs in that regard. There has been some indication that the rapid forward movement in this field might be curtailed by the lack of funding for this intramural research project. We believe that for the Cooley's Anemia patients this is an absolutely vital issue.

We were also very concerned with the statements made by NIH witnesses when they appeared before this Committee about the transfer of research money into the AIDS research program. As you may know, Mr. Chairman, over $11 million has been committed to the AIDS research program in fiscal year 1986 from NHLBI. All of those monies have been taken away from other activities, including research on Cooley's Anemia and other blood programs. We know of the importance of AIDS, and in fact are very concerned ourselves as all Cooley's Anemia patients need continuous blood transfusions. But we believe that money for AIDS research should be a "add on" on top of all other programs and not taken away from necessary blood programs that are now going forward.

Third, in regard to the National Institute of Diabetes and Digestive and

Kidney Diseases, we want to express the same concerns. Now that the sequestration program has been effected under Gramm-Rudman-Hollings for fiscal year 1986, we find that the losses there will severely restrict basic research programs in the hematology area at this institute. This institute has been extremely supportive of Cooley's Anemia research, and we would like to see funds restored to that institute so that it may continue forward on its basic research.

And, Mr. Chairman, while we are on the subject of the NIDDK, let us say that we fully and strongly support the concept that the hematology program in the institute be continued there. It has an important role in terms of basic research in that institute. We hope that that program will remain in that institute, and we know that it works very well with the blood programs in the National Heart, Lung and Blood Institute. We are aware that last year when the biomedical research authorization bill was agreed to by the Congress that one of the requirements in the legislation called for a study by the Director of the NIH as to whether all programs now in the NIDDK should be continued there. We want you to know that we are fully supportive of keeping the hematology program alive and well in that institute.

Fourth, Mr. Chairman, we want to express our appreciation to you for the bill report language that you provided a year-and-a-half ago which developed the first comprehensive Directory of State and Local Programs as well as Federal Programs which can assist Cooley's Anemia patients. A copy is appended to this testimony, not for the record but for your information. This Directory has been widely disseminated throughout the patient community.

Lastly, Mr. Chairman, we support the Ad Hoc Group for Biomedical Research Funding's request for the overall NIH funding of $6.07 billion.

Mr. Chairman and Members of the Committee, you have always been very supportive of Cooley's Anemia resaerch and care programs, and we are deeply grateful.

We would be pleased to answer any questions you may have.

Senator WEICKER. Thank you very much.

One brief question by me, and then if Senator Inouye has any.

What, in essence, has been produced by the research that is accountable for the increased longevity in lifespan?

Ms. GIORDANO. Let me answer that. The major research that they have found that is a lifesaver is a medication called desorxamine, which is an iron chelator. Because of our treatments, which are blood transfusions every 3 weeks, or every 2 weeks, depending on the patient, we have built up so much iron that it has actually suffocated our organs. Many of our patients die with heart disease, with heart dysfunction, kidney dysfunctions, diabetes, what-have-you, because the iron deposits in these organs. Desporel, as we call it, is used subcutaneously. It is in an infusion pump that the patients wear every night for 8 hours, and this chelates the iron, and removes the iron from the major organs, so that we are able to live longer. That is one of the major research.

Michael might like to say something.

Senator WEICKER. Michael is there anything or any next step that people are researching on now that is considered essential?

Mr. DEPHILIPO. They are working on an oral chelator right now, and they are working on gene transplants. As the national executive director of Cooley's, I wear two hats. I also have a 17-year-old son with Cooley's. So it is due to the money that you people have provided and the research. When Michael was first diagnosed, and I have known Vivian since she was a little girl, these children originally were told or the parents were told that they would not make it to puberty. We now have a 26-year-old young lady here, and I have a 17-year-old son, who without the research money that was supplied by you people, this would have never existed.

I am pleased to personally be here to thank Senator Inouye, because due to some of the bill language that he has written for us, we had a psychosocial directory printed that was long overdue, and it is now distributed all over the country. I personally thank you for your help because that directory has given our patients some flexibility that when they travel all over the country, they know where the facilities are to assist them in any problems they have. Without the money that you have provided, this would have never occurred.

Senator WEICKER. How many youngsters do you estimate, every year, are born with Cooley's? I gather that this is something that comes as a matter of birth?

Mr. DEPHILIPO. It is a genetic disease.

Senator WEICKER. How many do you estimate each year?

Mr. DEPHILIPO. We estimate that there must be 2,000 children born, but there are over 2 million carriers in the United States. We happen to be one of the smallest nations in the world with Cooley's. There is a new group called TIF, which is the Thalassemia International Foundation, and we find that there are 43 countries in this world with thalassemia. We happen to be one of the smallest, yet we are doing the most research of all of them.

Senator WEICKER. Senator Inouye.

Senator INOUYE. Mr. Chairman, it is always heartwarming to note that some of our efforts have borne fruit.

Before I close, I would like the record to show that the bill language that you referred to was drafted by the chairman's office, and he gave me the honor of presenting it.

I thank you both personally.

Senator WEICKER. It is just a simple little thing, and Senator Inouye is the man responsible. It is a simple little thing, at probably very little cost, and the tremendous benefit it has, I am talking about your directory.

Mr. DEPHILIPO. Our psychosocial directory.

Senator WEICKER. You have made a very eloquent presentation, I think, and we thank you very much.

Ms. GIORDANO. Thank you.

Mr. DEPHILIPO. We thank you for your time.

STATEMENT OF LEON W. HOYER, M.D., CHAIRMAN, RESEARCH COMMITTEE, THE NATIONAL HEMOPHILIA FOUNDATION, MEDICAL AND SCIENTIFIC ADVISORY COUNCIL

Senator WEICKER. Dr. Leon Hoyer, the chairman of the Research Committee of the National Hemophilia Foundation, Medical and Scientific Advisory Council.

Dr. HOYER. Senator Weicker, and Senator Inouye: I am associate vice president for Biomedical Research and Development of the American Red Cross, but I am speaking today for the National Hemophilia Foundation.

I am especially pleased to be here because this is the 10-year anniversary of Federal support for comprehensive hemophilia treatment centers. The National Hemophilia Foundation is grateful for this support over the past decade which has hasten the revolution in hemophilia treatment.

Federal support of comprehensive care, coupled with the availability of the plasma clotting factor concentrates, has made home infusion therapy possible, freeing patients from a life of hospital care and emergency room visits. There is no better example of the rapid translation of scientific advances into patient care.

The written testimony documents the impact of these comprehensive centers. There are now 31 centers and 60 affiliates and a strong regional network. Over 9,500 hemophiliacs, possibly half of the total population in this country, are served by these centers.

The impact has been dramatic. Between 1975 and 1985, the average number of hospital days per year per patient has been reduced by 80 percent, from 9.4 to 1.6. There has been a 73-percent reduction in the number of days lost from work or from school each year. These important human benefits have been accomplished through a program that has also led to significant economic savings.

Careful studies have documented that 74 percent reduction in total health costs per hemophiliac patient in 1985 compared to 1985. This is $223 million saved on a very small investment which has been $3.6 million in the past year.

There is no mystery about how these savings have been achieved. Comprehensive care prevents complications that require hospitalization, and keeps patients in the home and in school, and at work, rather than in the emergency room.

I have talked to you in previous testimony about the problem that has threatened hemophilia care, however, and that is the AIDS problem that you have heard so much about in the past 4 years.

I am sad to record, for this meeting, that there have 172 cases of AIDS among children and adults with hemophilia, and 99 have died. The recognition that AIDS is transmitted through blood products has had a profound effect on families affected by hemophilia.

It is with great sadness that I report that almost 1 percent of the patients with severe hemophilia have contracted this disease. More importantly, perhaps, is the recognition in the past year that unless preventative measures are utilized, 1 to 5 percent of the sexual partners of people with hemophilia will themselves convert to HTLV–III positive status each year.

It has reached the point where it is important to recommend risk reduction measures for all who have intimate relations with hemophilia patients. In order to reduce the transmission of AIDS in the hemophiliac community, it is important that accurate information be disseminatd rapidly through education and counseling. It is also important to dispel inaccurate information about AIDS, HTLV–III, and hemophilia.

These are the objectives that are being addressed by the treatment centers you created 10 years ago.

The issues I have addressed can be translated into the following requests for appropriations:

First of all, a major increase in the fiscal year 1987 appropriation for treatment centers. We urge that you appropriate $4.9 million to support these comprehensive care programs. While this is an increase, a significant $1.3 million increase over the current funding level, it is necessary if we are to address the 50 percent of the patients who are not now within the regional comprehensive program, and that this be retained within the 15 percent set-aside within the DMCH appropriations.

Second, that there be an emergency appropriation for risk reduction, education, and training so that our concerns about the risk of heterosexual transmission of AIDS can be addressed.

The Hemophilia Foundation is working with the CDC to develop a special program, and the information about this will be submitted to you within the next 2 weeks so that you can address it in bill language.

Finally, we urge the continued support of research. Hemophilia is not cured. Hemophilia is a less serious problem in some ways than before, but there are major problems that need to be addressed. We support the continuing support of the NIH in their efforts to provide this very important information.

PREPARED STATEMENT

In summary, the foundation has applauded and is grateful for the support of the Congress that it has provided for hemophilia research in the past 10 years. The results of this investment have been remarkable, but a serious and difficult problem remains, and we ask for your continued assistance.

Thank you.

[The statement follows:]

Statement of Leon W. Hoyer

I am Leon W. Hoyer, MD. I am the Associate Vice President of Biomedical Research and Development for the American Red Cross and I am speaking to you today as a representative of The National Hemophilia Foundation (NHF). I am the chairman of the research committee of NHF's Medical and Scientific Advisory Council.

This is the 10-year anniversary of federal support for comprehensive hemophilia treatment centers (HTC). NHF is grateful for the support that you have provided over the past decade for this program, and which as you are aware, has hastened a revolution in hemophilia treatment. Federal support of comprehensive care, coupled with availability of plasma clotting factor concentrates, has made home infusion therapy possible, freeing patients from a life of hospital care and emergency room visits. There is no better example of the rapid translation of scientific advances into patient care.

COMPREHENSIVE CENTERS - In 1976, the first year of Congressional support for the Comprehensive Hemophilia Diagnosis and Treatment Center Program, federal funding was provided to support the development of 24 comprehensive HTCs and 60 affiliates. Under the leadership of Dr. Merle McPherson of the Division of Maternal and Child Health (DMCH), the network of centers has expanded and now includes a strong regional structure. Over 9,500 hemophiliacs (nearly 50% of the total hemophilia population) are now served by these centers, which provide multidisciplinary services including psychosocial, financial and vocational counselling, in addition to medical, dental and orthopedic care. The impact of these programs has been dramatic. Between 1975 and 1985:

- the number of patients seen at primary treatment and/or affiliate center sites increased more than 343%;
- the number of patients in these regions receiving comprehensive care and the number on home care has increased nearly fivefold;
- the average number of hospital days per year per patient has been reduced by 80%; from 9.4 to 1.6;
- there has been a 73% reduction in the number of days lost from work or school each year;
- the percent of unemployed adults dropped from 36% to 9.4%; and
- the average costs of health care per year has been reduced from $31,600 to $8,127. (adjusted for inflation, in 1985 dollars).

These important human benefits have been accomplished through a program that has also led to significant economic savings. Careful studies have documented a 74% reduction in total health costs per patient in 1985, as compared with 1975. This $23,473 per patient savings represents an annual national savings of $223 million -- a handsome return on the federal government's $3.6 million investment. There is no mystery as to how these savings are achieved - comprehensive care prevents complications that require costly hospitalizations. In addition, comprehensive care prepares patients for home therapy so that they do not need 25-50 hospital visits each year for bleeding episodes.

Thus: Congress' investment in comprehensive care programs which promote home infusion therapy has paid off by reducing disability, unemployment and the cost of medical care for patients with hemophilia.

THE FUTURE OF HEMOPHILIA TREATMENT CENTERS - In 1981, HTC funding was included in the 15% set-aside for MCH funding. At that time, federal support of HTCs was $3.3 million. Last year, thanks to your support, the funding was increased to $3.6 million. The total funds available to centers in 1986 will be an increase of only 9% over the amount received five years ago. This increase helped to stabilize established services, but there are still 25 states that are not entirely covered by the regional federal treatment center network.

Two years ago, an ad hoc Advisory Panel to the DMCH Hemophilia Centers Program issued a series of recommendations concerning future directions of this program. The panel's report documented the need for increasing funding support for maintaining these centers, expanding psychosocial services, improving coverage to underserved areas through regionalization, improving third party reimbursement for the treatment of hemophilia, as well as identifying 11 areas requiring targeted special efforts. The need for and merits of comprehensive care were also cited in a 1985 report of the Office of Technology Assessment (See attached OTA citation).

AIDS: A SERIOUS PROBLEM THAT MAKES THE COMPREHENSIVE TREATMENT CENTERS EVEN MORE ESSENTIAL - Your Committee has heard much testimony about AIDS over the past four years. Of special concern is that, since July of 1982, there have been 172 cases of AIDS reported among children and adults with hemophilia, and 99 have died. The recognition that AIDS is transmitted through blood products has had a profound effect on families affected by hemophilia across our entire country. It is a stinging irony that these blood products, which have provided people with hemophilia with a newly found freedom from pain and disability, have been identified as the source of their vulnerability to AIDS. This crisis has created a need for comprehensive care that is greater than ever before. These centers, particularly with respect to the psychosocial care being provided, have served as anchors of support during this critical period - without them, there surely would have been widespread panic. But now, the need for risk reduction and psychosocial services is increasing more than ever before and will continue to do so in the immediate future because of the profound impact of data that has recently surfaced:

- one in every 115 individuals with hemophilia has contracted AIDS and, for those with severe hemophilia, the rate is one in 65;
- it is now known that 90% of persons with hemophilia have been exposed to the HTLV-III virus;
- two wives of men with hemophilia have contracted AIDS;
- it is estimated that, unless preventive measures are utilized, 1 to 5% of sexual partners of people with hemophilia will convert to HTLV-III positive status each year;
- one child of a man with hemophilia has contracted AIDS; and
- an increased number of AIDS cases have been reported in patients with mild and moderate hemophilia.

It has now reached the point where it is important to recommend risk reduction measures for intimate relations. In order to reduce the transmission of AIDS in the hemophilia community, it is important that accurate information be disseminated rapidly through education and counselling. It is equally important to dispel inaccurate information about AIDS, HTLV-III infection and hemophilia. These objectives are now being addressed by the treatment centers you created 10 years ago.

PROGRESS IN REDUCING THE RISK OF AIDS AMONG PEOPLE WITH HEMOPHILIA - As a result of enormous collaborative efforts between the public and private sectors, there has been substantial progress in reducing the risk of AIDS among patients and families affected by hemophilia. Blood donations are tested and blood products used by people with hemophilia are heat treated. Based on these advances, blood products used for treatment of hemophilia are virtually free of HTLV-III contamination.

Concern remains, however, about the large percentage of people with hemophilia who are antibody positive and the potential for the transmission of AIDS and/or HTLV-III infection to their sexual partners. Concern exists regarding the importance of people with hemophilia maintaining their treatment of bleeding episodes when medically indicated, despite their fear of AIDS. Special attention is also needed to address AIDS-related stress that is experienced by patients and families. But, most important of all, how many of the 90% of the people with severe hemophilia who are HTLV-III positive will succumb to AIDS?

APPROPRIATIONS REQUEST - The issues that I have addressed can be translated into the following requests for appropriations:

1. FY87 Appropriations for Treatment Centers - We urge you to appropriate $4.9 million for FY87 to support the HTC Program. While this is a $1.3 million increase over the current funding level, it is essential if we are to adequately address the needs of 50% of the patients not now within the regional comprehensive care programs established by DMCH. These funds would be used to expand the existing regional network to areas not currently served. To assure the continuation of these programs, we request that you retain the 15% level for a set-aside within the DMCH appropriations, because it is more efficient to distribute resources for certain disorders on a regional and national basis, rather than through block grants through states. The HTC Program is clearly a special program of regional and national significance and is a model for other chronic diseases. We also urge that MCH, of which the hemophilia program is a part, be funded at the full authorization level, as this is an investment in our nation's future.

2. Emergency Appropriations for Risk Reduction, Education and Training - Now that the blood supply is no longer considered a source of HTLV-III transmission to the hemophilia community, the major concern is the potential risks associated with heterosexual transmission of AIDS and HTLV-III infection. The development of risk reduction strategies for the hemophilia population has added importance at this time, as there is increasing public concern about the heterosexual transmission of AIDS. The hemophilia community represents a model for heterosexual transmission, as its population is amenable to surveillance and is relatively self-contained and stable, with the highly regionalized services that are concentrated in the federally supported HTCs. To effectively reduce the risk of heterosexual transmission of AIDS/HTLV-III infection, it is important that the health education and behavioral change experiences of the hemophilia community be well understood and documented. These efforts among people with hemophilia will be of benefit to the general public during the AIDS epidemic.

AIDS has also caused considerable fear and confusion among patients, health professionals and the general public. The potential of heterosexual and perinatal transmission has had a profound social and psychosocial effect upon individuals and entire families. In some instances, due to the fear of AIDS, some patients have withheld treatment when medically indicated. What a tragedy it would be if the fear of AIDS were to catapult us back two decades, to the era of substantially increased bleeding causing deaths and severe joint damage. And, because most people with hemophilia are HTLV-III positive, it is of great importance that accurate information is provided so that there is not undue alarm in work, school and social settings. To assist us to address these risk reduction, psychosocial, education, and training needs, we are requesting the special appropriations in the amount of $4.3 million to the Centers for Disease Control. It is anticipated that CDC would distribute the majority of funds through the existing network of regionalized HTCs. Within the next several weeks, we will be bringing further information to you to seek your guidance as to how support for these urgent needs can best be accomplished in FY87.

3. Research - The success of comprehensive care and home infusion therapy might suggest that the "hemophilia problem" has been solved. Nothing could be further from the truth. Hemophilia is still an extremely painful and disabling disease. Clotting factor can effectively control bleeding but it is not a cure. And the AIDS tragedy has re-emphasized that, as long as people with hemophilia depend upon a factor derived from human blood plasma, they will be vulnerable to anything that may contaminate blood products. In addition, clotting factor inhibitors develop in over 10% of hemophilic patients and these antibodies seriously compromise subsequent care. For these reasons, we are vitally concerned that there be adequate funding for basic biomedical research supported by the NIH, and especially the blood diseases and resources research program of NHLBI and the important research conducted by NIADDK and NIAMSD. We are also grateful for Congressional support for increased AIDS-related research. Continued and increased funding is needed in this area. The NIH, including NCI, NIAID, and NHLBI must receive sufficient funding to support a multifaceted research effort that will lead to a better understanding, control, and widespread distribution of experimental drugs through the regionalized network of HTCs when promising results occur in phase I and phase II trials now being conducted at NIH. Additionally, the Centers for Disease Control need increased funding so that they can expand their excellent laboratory investigations and epidemiologic studies and the FDA needs support to expand their surveillance of the safety of blood products.

SUMMARY - Over the last ten years we have been most pleased with the support you have provided for hemophilia research and treatment. The results of your investment have been remarkable. But today, we are faced with very serious and difficult problems as a result of AIDS. Therefore, we are asking you to help us find more support for comprehensive care, research and addressing the unique problems faced by the hemophilia community as a result of AIDS.

Thank you.

OFFICE OF TECHNOLOGY ASSESSMENT

Blood Policy and Technology (Washington, DC: U.S. Congress, Office of Technology Assessment, OTA-H-260, January 1985

OTA on Medicare and Hemophilia:
"Opportunities exist for improving health care provisions for hemophiliacs, if not by creating a special program for them, then by providing coverage for blood products on an outpatient basis." (The OTA Report recommended expanded coverage for hemophiliacs, pointing out the inadequacies of Medicare which determines eligibility on a case-by-case basis; instead of by universal entitlement.)

OTA on Comprehensive Care and Hemophilia:
"The situatiion for hemophiliacs has improved dramatically since passage of Public Law 94-63 in 1975." (Federal support of regional comprehensive hemophilia treatment centers.)

OTA on Cost Savings and Hemophilia:
"Compared to the year before the programs had started, the cost of total care, including rates of hospitalization, has been reduced, and unemployment among hemophiliacs is lower."

OTA on Other Economic Benefits and Hemophilia:
"The proportion of patients with third-party coverage has also grown, both because employment of hemophiliacs increased as a result of better treatment, and because health care workers at the centers have helped patients arrange for coverage."

Senator WEICKER. Thank you very much.

Just one brief question. Have the new blood screening techniques assisted in this problem that you have cited vis-a-vis AIDS and blood transfusions?

Dr. HOYER. This has been a major step forward, especially for patients who receive single blood transfusions. In the case of hemophiliac care, this has made the precipitate donor units much safer. Of course, for hemophiliacs receiving the concentrates, this is now all heat treated, and that has had a major effect also on the transmission of the AIDS virus.

We are living with the problem that occurred over the 5 years before these steps were taken.

Senator WEICKER. Senator Inouye.

Senator INOUYE. Is there any possibility of genetic prevention of the disease?

Dr. HOYER. Yes; I think, way down the road, when we understand how to introduce genes, and how to change the genetic structure in the way of preventing these disorders, yes, but that is way down the road and will need continued research.

Senator INOUYE. Thank you.

Senator WEICKER. Thank you very much.

Dr. HOYER. Thank you.

STATEMENT OF ALAN D. SCHREIBER, M.D., MEMBER, AMERICAN SOCIETY OF HEMATOLOGY

Senator WEICKER. Our next witness is Dr. Alan D. Schreiber, a member of the Public Education Committee of the American Society of Hematology.

Dr. SCHREIBER. Thank you, Mr. Chairman.

As you know, I represent the American Society of Hematology and its more than 3,000 members. We are the only national organization for hematologists which represents physicians involved in the treatment of blood disorders, and the biomedical researchers in our country involved in the research related to the blood and blood diseases.

What I would like to outline for you this morning, in the few minutes that we have available, the four major areas in which our members have made major contributions over the last year or two in blood and blood disorders. We will talk about AIDS, leukemia, heart disease and stroke, and cancer.

Some of my colleagues recommended that I should bring a tube of the AIDS virus with me right here. I elected not to do that, I thought that everyone might leave the room. But we have made tremendous progress over the last couple of years in terms of AIDS.

First of all, we have isolated the virus. We have determined the cell that it affects. It affects the blood cell, a T-lymphocyte. We have determined how it affects the cell. We have determined what it does to the cell, how it makes the cell dysfunctional, and how it, therefore, alters the cell.

We have made major contribution in determining how to detect the virus, material that has been infected by the virus, so that we can control the spread of this disease. We have determined how to screen for it so that we can screen blood product, so that your children, your spouse, your relatives can receive a blood transfusion without fear of getting AIDS.

This is a tremendous accomplishment which otherwise the disease would spread through the population like wildfire. We have made tremendous progress in AIDS over a short period of time.

The virus that causes AIDS, which is called HTLV type III, it is called HTLV because it is human T-cell leukemia virus. Human T-cell leukemia virus type III is directly related or closely related to human T-cell leukemia virus type I, that is the virus that has been the first virus shown to cause leukemia in humans. The first virus shown to cause a cancer in man, HTLV–I. This is a very important observation.

This leukemia occurs in clusters. Now we understand what causes it. We understand the viral cause, and there is exciting work going on to control the ability of the virus to infect cells, and clinical studies undergoing to treat the disease by understanding what causes it and preventing the virus to infect cells and the proliferation of these cells.

In addition, atherosclerosis and cardiovascular disease and stroke, we now know that blood cells, certain blood cells like platelets, bind to the blood vessel wall, and they release growth factors such as a platelet derived growth factor, which has recently been isolated, which causes the proliferation of blood cells within the blood vessel wall. This proliferation of blood cells, or blood elements in the vessel wall, is very important to the development of atherogenesis and, therefore, heart disease and stroke.

The isolation of growth factors, and its understanding of the control of proliferation of blood vessel wall elements, is a major step forward in understanding what causes heart disease and stroke, and gives us a new avenue that we can approach novelly the control of heart disease and stroke.

These growth factors have made another important advance in terms of our understanding of malignancy, because we now know that these growth factors are under the control of very specific genes which are called oncogenes. The control of the expression of oncogenes, the regulation of turning on oncogenes and turning off oncogenes, we now know, are the very roots of the cause of cancer.

This is a major discovery that has occurred over the last couple of years, and will surely receive international recognition in the future. Oncogenes, the understanding of the molecular biology of cancer, is going to provide us with an opportunity to deal with cancer and the treatment of cancer, surely in very exciting ways, in the future.

What we need to approach and continue unabated these areas in AIDS research, in leukemia, in atherosclerosis, in heart disease and stroke, and in cancer is to have our individual investigator related, nondirected research supported at the 6,000 RO–1 level. We need the 6,000 RO–1's, and we need the fiscal year 1987 budget at the $6.1 billion level.

PREPARED STATEMENT

In addition, as you can see from the fact sheet you have in front of you, which I handed out, we have the other important matters that we need to have dealt with.

This exciting war, this military activity that we have going on against human disease, moving at the rate at which it is moving now, it makes it a very exciting time in biomedical science.

[The statement follows:]

Statement of Alan D. Schreiber

On behalf of the American Society of Hematology and its more that 3,000 members, I thank you for the opportunity to present testimony before the Subcommittee again this year in connection with the legislation for the fiscal 1987 appropriations for the National Institutes of Health.

I am here today representing the Public Education Committee of the American Society of Hematology. This Society is the only national organization of hematologists and is made up of physicians and biomedical scientists who are concerned with research, patient care and teaching as they relate to blood.

Before presenting our views about this legislation, I would like to express my deep gratitude to the members of this Committee and to the entire Congress for their very strong support last year on behalf of biomedical research and hematology. We greatly appreciate your long-standing commitment to the programs of the National Institutes of Health. We are particularly pleased with the strong support given by the Congress to investigator-oriented research. The creative imagination of our nation's scientists represents one of our country's greatest natural resources. The support that you have directed to these scientists provides the raw materials upon which their ideas will flourish.

The fluid and cellular constituents of blood are critical in maintaining many of life's processes. Flowing as they do through every organ of our body, abnormalities of the blood affect many organ systems. It is natural, therefore, that blood research is supported by a number of institutes, particularly the Heart, Lung and Blood Institute, the Cancer Institute, and the National Institute of Diabetes, Digestive and Kidney Diseases. This spectrum of support has been most productive for hematology research and for the broad research mandates of the individual institutes, and we feel strongly that each of these institutes should continue to direct funds for the support of blood research.

AIDS is a good example of a disease transmitted in blood that affects one of the important blood cells, the lymphocyte. Its manifestations are seen in the dysfunction of many organ systems. Hematologists have been among the scientists leading the way in identifying the AIDS agent, defining the biologic processes through which it acts, and now working to identify means of controlling this process. Support for hematologists conducting AIDS research has been provided by each of the three institutes just named. The great progress in the understanding of AIDS made thus far is a credit to the organization of the NIH itself and to the strong partnership which exists between the NIH and the many scientists making up the biomedical research community. The system works. Recent Congressional action has directed that funds for AIDS research, including funds within the NIH, be redirected to the Office of the Assistant Secretary for Health. We believe that the proper place for AIDS research funds is within the NIH and not within the Office of the Assistant Secretary. We urge the Congress to redirect research funds properly the province of the NIH back to the NIH. While we respect the need for coordinating various aspects of AIDS research, including fundamental biology, epidemiology and therapy, we wish to emphasize that progress in this disease has occurred at a rate unparalleled in the history of human discovery, and that progress has been made under the effective and enlightened guidance of the NIH. We urge the Congress to ensure that the research success of the past will continue in the future under the aegis of the National Institutes of Health.

In order for the NIH to be effective and to be responsive to the biomedical research community it must have flexibility. We are concerned that the distribution of funds within institutes as required by the Office of Management and Budget impairs that flexibility. If the NIH in general, and the individual institutes in particular, are to be responsive to the shifting needs in biomedical research, needs which the NIH leadership understand very clearly, that leadership must have the flexibility to move funds as they and their advisory groups deem best.

Over the past year enormous progress has been made in many areas of hematology research. We have learned a great deal about the adhesive qualities of blood platelets, cellular elements which are so important in controlling bleeding.

We also know that the adhesive qualities lead to excessive blood coagulation, which results in strokes and in heart attacks. We hope that this new knowledge of the adhesive qualities of platelets will lead to therapies which will control these devastating diseases.

Work on the synthesis of hemoglobin, the molecule within red blood cells responsible for carrying oxygen, has led to a new plateau of understanding about the genetic control of protein synthesis. Work on the hemoglobin genes over the past decade forms much of the foundation for our current level of research in molecular biology. Efforts of hematologists are targeted on a number of important diseases, particularly sickle cell anemia and Cooley's anemia.

Exciting discoveries concerning specific genetic abnormalities in the human leukemias have helped in defining a set of genes which we know now to be critically important in normal growth control and which, when functioning abnormally, fuel the malignant process. These genes have come to be known as "oncogenes". Many share with me a confidence that, with our understanding of the genetic abnormalities responsible for malignant disease will come new strategies for conquering cancer.

Aplastic anemia, a progressive and usually fatal disease typically resulting from an unexplained failure of the bone marrow to produce blood cells, is now frequently treated successfully with drugs that affect the immune system. In other patients, bone marrow transplantation offers the hope for long-term cure. We have seen the technology of bone marrow transplantation extended to the therapy of patients with acute leukemia. This technology, which heretofore has relied on bone marrow donated by siblings of the affected individual, has now been expanded to the use of unrelated compatible donors found in large computer searches of individuals who have been typed by some of our leading blood transfusion centers. This expanded pool of potential bone marrow donors opens new horizons for individuals who do not have suitable family members who might serve as donors of normal bone marrow. This new approach is not without many pitfalls, but we believe that research now ongoing will overcome many of these pitfalls and extend the technology of bone marrow transplantation even further.

These are only some of the important advances in hematology research. The biomedical research community has climbed to enormous heights of new knowledge. The explosion of biomedical technology it has created continues to catapult this process. Increasingly difficult questions are being approached, and increasingly difficult answers are being found. This is a costly process. It is costly in dollars, and it is costly in personal commitment. The new knowledge acquired not only forms the basis for future biomedical discovery, it provides the foundation for new biomedical research industries which are creating jobs for many of our citizens and breathing new life into many of our heretofore aging cities. Our nation's investment in biomedical research has become not only an investment in the future health of our loved ones, it has become an investment in the health of our economy. The investment has been in basic, investigator-initiated, non-directed, creative research. It is to this research that the energies of the NIH must be directed. The current success of this research and its promise of future successes are strong imperatives for support of NIH research at a level of no less than $6.1 billion for fiscal 1987.

The American Society of Hematology makes the following recommendations, and expresses concerns as follows:

1. That appropriations for FY 1987 for the National Heart, Lung and Blood Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases be funded at a level of at least "maintenance of effort" levels, based upon the pre-sequestration FY 1986 appropriated funds, with sufficient increase to account for inflation.

   Suggested levels:

   NHLBI: $950.3 million
   NIDDK: $504 million

2. That blood transfusion centers, called for in the appropriations bill report language last year, be funded in FY 1987 at the peer review recommended level (particularly important because of the AIDS public health threat).

3. That AIDS funding be an add-on, and not taken from on-going programs (in FY 1986, in order to fund AIDS research, the percentage of blood research funding decreased from 17% of the NHLBI budget to about 15%), in FY 1987.
4. That Congress carefully consider the impact of the proposed movement of funds from the Institute level for AIDS research to the office of the Assistant Secretary for Health. It is at the Institute level, and the NIH level, that scientific understanding of opportunities is best understood and followed. There is no need for a "czar" over AIDS research; there is concern that insufficient scientific experience would be present in ASOH; and there is concern that decisions at that level would be open to potential political, rather than scientific, influence on decisions.
5. That the appropriations process, which can affect program decisionmaking at the institute level, be informed that this Society supports the continuation of the excellent hematology research program at the NIDDK as it is presently constituted.

   Last year's biomedical research authorization law carried language requesting the Director of NIH to study the structure of the NIDDK to determine whether some programs would be better administered if shifted to other institutes. This Society has studied the matter and expresses its belief that hematology research programs in the NHLBI and NIDDK are both excellent, and mutually supportive, and coordinated in such a fashion that there is not overlap of research. We have expressed this opinion to NIH.
6. That the Institutes of the NIH be permitted to retain the flexibility they require in terms of movement of funds between mechanisms of support as scientific opportunities present themselves. We oppose strongly OMB's attempts to limit this flexibility.

Thank you.

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6. That the Institutes of the NIH be permitted to retain the flexibility they require in terms of movement of funds between mechanisms of support as scientific opportunities present themselves. We oppose strongly OMB's attempts to limit this flexibility.

Senator WEICKER. Dr. Schreiber, thank you very much for your testimony. Let me say this, I appreciate the good wishes of your colleagues with the AIDS virus, but I think I want to make a point clear here, and I think that it is terribly important for the Nation as a whole. This budget that was presented by the administration as it relates to NIH is $400 million less than what this committee appropriated last year, and I think that it is time that this country announce what its priorities are to the people who are continually trying to undercut the business of life, which is your business and the business of this subcommittee.

Indeed, this subcommittee thanks the full Appropriations Committee, under Senator Hatfield, and also the eloquence of Senator Hatfield, that we have managed to at least hold our own, which to me is not holding very much in terms of research, which we should be far ahead on.

I say these things because there are an awful lot of people who are being taken in as to what constitutes the strength of the United States of America. I think that our great strength will always be our preoccupation with life, and not death. Right now we are preoccupied with death in many forms.

I can assure you that we will do everything that we can. I think that this is very dramatic testimony, including the necessity to increase funding in this area.

Senator Hatfield.

Senator HATFIELD. I certainly associate myself with the excellent statement of the chairman.

Senator WEICKER. Senator Inouye.

Senator INOUYE. Just one question, sir.

Is the blood screening process for AIDS a very complicated and expensive process?

Dr. SCHREIBER. It is expensive and somewhat complicated, but as technology improves, and it is moving at a very rapid rate, it will become less expensive and less complicated.

Senator INOUYE. So it is not feasible for the man on the street to have an AIDS test whenever he has a blood test.

Dr. SCHREIBER. Not without some financial support.

Senator INOUYE. How much would it cost?

Dr. SCHREIBER. I can't give you a dollar figure, but it is not within the realm of reasonable laboratory procedures.

Senator INOUYE. It is not like testing for cholesterol.

Dr. SCHREIBER. No; it is more expensive than testing for blood cholesterol. But the rapidity at which the field is moving and the excitement in the biomedical research field, not just in the AIDS, but in the other areas that I mentioned, leads one to not only make these major contributions as we move ahead, but also reduce the price of testing, of course, because of more simple, more direct, more manageable diagnostic procedures and therapeutic procedures are being developed almost daily.

Senator WEICKER. Thank you very much.

STATEMENT OF ARLENE PESSAR, R.N., EXECUTIVE DIRECTOR, DYSTROPHIC EPIDERMOLYSIS BULLOSA RESEARCH ASSOCIATION

ACCOMPANIED BY:
JENNIFER CALDWELL
RAY CALDWELL

Senator WEICKER. Our next witness is Arlene Pessar, the executive director of Dystrophic Epidermolysis Bullosa Research Association. I know that we have been very supportive, but I still can't say the words.

It is nice to have you here. Who is your young friend, and who is the lovely lady that you bring with you?

Ms. PESSAR. The lovely lady is Jennifer Caldwell of Virginia Beach, and this is her son, Ray.

Senator WEICKER. Hi, Ray.

Ray CALDWELL. Hi.

Senator WEICKER. How are you doing?

Ray CALDWELL. All right.

Senator WEICKER. Senator Hatfield.

Senator HATFIELD. Mr. Chairman, I am very happy to be able to join you this morning in receiving the testimony of Arlene Pessar. who is the founder of the citizens organization that has brought a new awareness to this problem of epidermolysis bullosa [EB]. She is the mother of an EB child as well, and she has both the personal experience, and then organized a group of people across this country around the cause of EB. Last year, she received about 15,000 telephone calls and letters and communications of all kinds.

She has not only been the dynamo behind it, but she certainly has become an authority and speaks with great understanding.

This, as you know, is one of the things that you, Mr. Chairman, and this subcommittee have responded to where there was no money for research. There is now an item in this budget for research. It has brought forth a new focus by medical schools, research institutions, medical students who are now addressing this subject where there was little attention given to it before.

All of us are grateful to you, for your leadership in entering this item into our budget. We are hoping that this year we can not only keep that item in the budget, but to hear today from Ms. Pessar about some of the progress that has been made as a result of such funding.

Ms. PESSAR. Thank you, Senator Hatfield, and Mr. Chairman.

I am happy to be here again, to have this opportunity to testify. This past year, as the Senator has pointed out, has been filled with excitement and unprecedented opportunities in epidermolysis bullosa. Truly, it is because of your concern and commitment, and the commitment of the people on this committee to expand research on EB that has made this extraordinary progress possible.

On behalf of the thousands of victims and parents who suffer from epidermolysis bullosa, like Jennifer and myself, I want to express my deepest gratitude and appreciation to all of you, and each of you, and to all the members of the committee, and the aides for the strong support of this effort.

I introduced Ray Caldwell. Ray is 6 years old and suffers from a form of EB commonly referred to as EB letalis. Because most children born with this type of EB usually die in infancy, we think of Ray as a miracle child because he truly has defied the odds. Each of you and your colleagues in the Congress, past and present, can and should take credit for this miracle.

Ray is here with us today and living a normal life only because of your long-standing commitment to the NIH and its research programs.

When Ray was born, he was missing large areas of skin on his face and body. I have a before picture, which is a little bit shocking. These areas were severely painful and disfiguring, and because of the susceptibility to infection, and they were also life threatening.

During the past year, these raw areas were treated with skin grafts consisting of cells obtained from Ray's own skin and grown into sheets in the laboratory. This procedure, pioneered by NIH grantees at the Massachusetts Institute of Technology and Harvard in the 1970's to help patients suffering from severe skin ulcers and burns, has been successfully used on three patients now with EB letalis.

Additional research and money is needed to determine if this therapy can be used for the EB population at large.

In addition to this work being done at Rockefeller, I would like to update you on some of the other progress being made, and I have here a news release put out recently by the NIH on these new grants.

In accordance with this committee's directive to intensify research on EB, and utilizing the $750,000 provided by the committee, the National Institute of Arthritis, Musculoskeletal and Skin Diseases has awarded 10 new grants to investigate EB. We are optimistic that this basic research will bring promising new findings which will one day improve the quality of life for all who suffer from this and other serious diseases of the skin.

One of these grants is to support a conference on the nondermatologic consequences of EB. Although a great deal has been learned about the basic underlying defects, virtually little is known about lesions affecting the eyes, mouth, esophagus, intestines, respiratory, and urinary tracts.

By addressing the state of the current understanding, we hope to put together the critical information that until now was considered anecdotal in nature.

In addition, the new institute will be supporting a national EB registry later this year. The registry will gather information on the genetics of EB and help to focus on new avenues for research and treatment.

To consolidate and build on all this recent success, we hope that the committee will continue to give high priority to research relevant to EB.

Today, the members of DEBRA, along with other members of the coalition addressing the concerns of the new National Institute of Arthritis, Musculoskeletal, and Skin Diseases, are here as advocates in support of this newest National Institute of Health. We are hopeful that even in these stringent economic times, the committee will approve the recommended $151,650,000 to establish the new National Institute of Arthritis, Musculoskeletal, and Skin Diseases as a fully functioning research entity.

Included in this recommendation is $2.4 million to support six core centers in dermatology. We strongly endorse this recommendation, and urge you to appropriate the funds to develop these six centers.

We also ask and hope that you will recommend that at least one of these dermatology centers be developed with a research emphasis on EB.

Mr. Chairman, I believe that one day there will be a cure for many of these tragic diseases. It might not be this year, but with your continued commitment and support, I do believe in my heart that we will see it in our lifetime.

PREPARED STATEMENT

I thank you for your compassion and concern.

[The statement follows:]

STATEMENT OF ARLENE PESSAR

SUMMARY OF RECOMMENDATIONS

1. That FY 1987 appropriations for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) be set at a level of, at least, $151,650 million. This is the minimum level needed to establish this new Institute as a fully functioning research entity.

2. That $2.4 million be appropriated to support six core centers in dermatology. That, at least, one center be developed with a strong research emphasis on Epidermolysis Bullosa and related diseases.

3. To build on and consolidate the recent advances, that research on EB continue to be intensified and receive high priority.

This year has been a year of unprecedented opportunity for Epidermolysis Bullosa (EB). Your support and commitment to stimulate and expand EB research has made this extraordinary progress possible.

On behalf of thousands of EB patients and families all over the country, and the world, who suffer from this group of severe blistering skin diseases, I would like to express my deep gratitude and appreciation to you and the members of the subcommittee for your strong support of this intensified effort.

I am Arlene Pessar. I am the founder and executive director of the Dystrophic Epidermolysis Bullosa Research Association of America (D.E.B.R.A.). My 15-year old son, Eric, suffers from a severe form of epidermolysis bullosa.

D.E.B.R.A. is a young organization dedicated to the improvement in the quality of life for all EB patients and their families.

Epidermolysis Bullosa (EB) is a group of inherited disorders in which the skin and mucous membranes are so fragile that the slightest touch may cause painful blistering. EB, a life-long disease often present at birth, causes severe physical, emotional and financial hardships for the affected persons and their families.

This year I am accompanied by Ray Caldwell of Virginia Beach. Ray is six years old and suffers from a form of EB, commonly referred to as EB letalis (EB junctional), because most children born with this form of EB usually die in infancy; or if they survive lead very restricted lives. We think of Ray as a "miracle child" because he has defied the odds! Each of you, and your colleagues in the Congress - past and present - can, and should, take credit for this miracle.

Ray is here with us today and living a normal life because of your long-standing commitment to the NIH and its research programs.

During the past year, Ray has been treated by Dr. D. Martin Carter and his associates at The Rockefeller University, New York City, using a therapy that was pioneered by NIH grantees at the Massachusetts Institute of Technology and Harvard in the 1970's to help patients with severe skin ulcers and burns.

Ray was born with large areas of skin missing on his face and body. These areas of denuded skin were severely painful and disfiguring. Because of the potential for metabolic imbalance and susceptibility to infection, they were also life-threatening. Inspite of intense therapy at several medical centers throughout his life, little could be offered to help Ray.

During the past year, these raw areas were treated with skin grafts consisting of cells obtained from Ray's own skin and grown into sheets in the laboratory. After repeated grafting, Ray's facial skin is now completely normal except for some loss of pigment. But even this is now returning and will continue to improve with time. With healing of his facial skin, it became possible for Ray to undergo surgery to correct abnormalities of his eyelids and nose caused by EB. Now for the first time in his life, Ray is facing the world with skin instead of raw open patches on his face.

This procedure has been successfully used on three patients with EB junctional. Additional research is needed to determine if this therapy can be used for the EB population at large.

The General Clinical Research Centers (GCRCs) provide the kind of specialized environments required to study and treat complex human diseases like EB. We urge you to continue to vigorously support the vital and outstanding programs funded under the auspices of the Division of Research Resources.

In addition to the work being done at The Rockefeller University, I would like to update you on some of the other progress that has been made during the past year in EB.

In accordance with this committee's directives and wishes to intensify research on EB, the National Institute of Arthritis and Musculoskeletal and Skin Diseases has dramatically increased its initiatives to stimulate more research. As a result of a solicitation on EB and the biology of the basement membrane zone, and utilizing the $750,000 provided by the committee, ten new grants were funded. We are optimistic that these basic research grants will bring promising new findings which will - one day - improve the quality of life for all who suffer from EB and other serious diseases of the skin.

One of these new grants is to support a conference on the non-dermatologic complications of EB. Although a great deal has been learned about the basic biochemical and structural integrity of the skin, virtually little is known about lesions affecting internal organs, such as the eyes, mouth, esophagus, gastrointestinal, respiratory and urinary tracts. Chronic blistering and scarring in these organs often results in painful medical complications, disability and early death.

By addressing the state of the current understanding of EB, we hope to pull together critical information that until now was anecdotal in nature. This should also help to focus on new avenues for research and treatment.

In addition, this year the Institute will be supporting a national EB registry. The registry will serve to increase information on the genetics of EB, improve methods of diagnosis and prenatal diagnosis, and develop new therapeutic modalities for the different types of EB.

To build and consolidate on all this recent success and take advantage of the great potential for major research advances, we urge the subcommittee to continue its commitment and give high priority to research relevant to EB in its final report to the Congress.

Today we at D.E.B.R.A., along with the other members of this coalition, are here as advocates. The establishment of a new National Institute of Arthritis and Musculoskeletal and Skin Diseases provides an extraordinary opportunity to address the health needs of millions of people who are victims of the serious and debilitating diseases funded under this Institute.

We are hopeful that even in these stringent economic times, this committee will continue to exercise its wise and caring judgment and appropriate the funds necessary to establish this Institute as a fully functioning research entity. We fully support and endorse the coalition's budget recommendations and urge you to approve a funding level of, at least, $151,650 million in FY 1987 for the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Included in this budget recommendation is $2.4 million to support six core centers in dermatology. Today the state of science in dermatology, generally - and EB specifically - is at a point that would greatly benefit from the concentrated interdisciplinary effort that bring clinical and basic research capabilities together. We strongly endorse this $2.4 million recommendation and urge you to appropriate these funds to develop these six centers. We also hope this committee will recommend that, at least, one of these dermatology centers be developed with a strong research emphasis that relates to EB.

Mr. Chairman, I believe one day there will be a cure for many of these tragic diseases. It might not be this year, but with your continued commitment and support, I know we will see it in our lifetime.

Thank you for your compassion and concern. Your support has made a difference. I urge you to continue to make a difference.

Senator WEICKER. Thank you very much.

Senator Hatfield.

Senator HATFIELD. Mr. Chairman, I wonder if Ray or his mother might have some words to add before I ask the questions that I would like to ask.

Ms. CALDWELL. I would like to add that I appreciate everything that has been done, and especially by this organization and this committee, because this has brought a more positive input in our lives, so he could have a better and more productive way of life, and get back into the main stream of life. For that, I thank you all.

Senator WEICKER. Ray, where do you go to school?

Ray CALDWELL. I have a home-bound teacher.

Senator WEICKER. What is your favorite thing to learn?

Ray CALDWELL. Take away, subtraction.

Senator WEICKER. What do you like to do outside best? Do you like to play?

Ray CALDWELL. Yes.

Senator WEICKER. What do you like to play most?

Ray CALDWELL. Running.

Senator WEICKER. Do you like to work at home, or do you like to play outside?

Ray CALDWELL. To work at home.

Senator WEICKER. Good for you. [Laughter.]

You are just terrific, Ray.

Senator Hatfield.

Senator HATFIELD. Arlene, have we had good cooperation from NIDDK in this new research program that has been launched?

Ms. PESSAR. Absolutely. I think they have done everything possible, really, within their power to initiate. They have issued several program announcements, and the responses to those have just been wonderful. We have a new researcher in your hometown now, who was funded this year. There is another one, who was not funded under the NIDDK, but through the Dental Institute in Connecticut. So everybody is getting their share, and I think that everybody has just been wonderful.

I think that it is exciting because the new institute, especially for people in dermatology, we were like little neglected skin diseases, had really been neglected for such a long time. I think the focus on skin in the new institute is just going to open up wonderful, new exciting doors for all of us.

Senator HATFIELD. Do you have any idea how many applications for research grants were made compared to the amount that they had to grant?

Were there more, or did they have to solicit to generate interest, since this is such a new field?

Ms. PESSAR. For epidermolysis bullosa?

Senator HATFIELD. Yes.

Ms. PESSAR. Yes; they did. They put out—their first program announcement was sent out about 2 years ago, and the response to that was negligible. The second one, I think they received somewhere around 16 or 18 applications, and 10 of them were fundable within the scores, within the peer review system, and the allotted pay lines.

Senator HATFIELD. The level of funding for this coming year that you had, do you think it is adequate to cover potential research grants, as well as continuations?

Ms. PESSAR. That is what the coalition, who really makes these recommendations, the $151 million would be adequate. My personal opinion is that it is never enough, you know.

Senator HATFIELD. Except for the point that I am trying to make here. If we appropriated money and there are not people and institutions interested in doing this research, then the money just sits there.

Ms. PESSAR. No; I don't believe that.

Senator HATFIELD. I am trying to find out if we have more applications now, since this has become more understood as an area of research, if there are more applications now than we are able to accommodate.

Ms. PESSAR. Absolutely.

Senator HATFIELD. We started with zilch.

Ms. PESSAR. Exactly.

Senator HATFIELD. Now we have built up to a point where there is a great deal more interest than we are able to grant.

Ms. PESSAR. Yes; I think the field of dermatology as a science is up to a level that more basic research can be done on EB, and not only on EB, but it relates to so many other areas, and vice versa. Research one disease also related to EB.

There are definitely a lot more scientists out there who would do work on this disease if the funding were made available.

Senator HATFIELD. What about the matter of research into drugs that would relieve the pain, how is that progressing?

Ms. PESSAR. I don't know. My personal feeling is that it is a little bit slower. Maybe Dr. Peyton Weary could address that.

Dr. Weary, can you give any information?

Dr. WEARY. In terms of medication for pain.

Ms. PESSAR. Any new drugs, I guess, is that what you are asking, on the horizon that might be applicable to EB?

Eric, my son, is under experimental drugs right now. It is an ointment that really is wonderful, and it is seeking FDA approval. It is being used on skin infections and skin ulcers, and it seems to be very promising. It is a drug by Beecham. If there is anything else out there, I don't know.

Dr. WEARY. Nothing that is at a stage where we can say that it is well-established. But we are learning a lot more about the basic type of physiology.

Ms. PESSAR. I think perhaps the new retinal aides, the vitamin A derivatives, might have some implications to EB, but very little work has been done in that area. There are a lot of new dressings.

Senator HATFIELD. Mr. Chairman, I have no other questions, I only want to say that I think we are really on the frontier here, and pioneering some exciting work and that gives a great sense of satisfaction to know that we have been able to be helpful. I know I speak for both Chairman Weicker and myself.

Senator WEICKER. I thank you very much.

Ray and Jennifer, thank you very much.

Ray, when you walked in this room, and I saw this nicely dressed young man and handsome fellow, I said, who is that? Now I know, and it was just a great pleasure having you here. Are you going to come back and visit us again?

Ray CALDWELL. Yes.

Senator WEICKER. I would like that. Thank you very much.

Ms. PESSAR. Before I leave, I have special regards from Cal Larson, whom most of you know. Cal was just not feeling well, and was not able to join us today. His parents are here, and he sends you thanks, regard, and gratitude.

Senator WEICKER. We have great gratitude, I might add, to you and to so many others who come here, and who make real the needs of America.

I am blessed also. I have a reputation of being a hardnose, and Senator Hatfield has a reputation of being a really nice guy. [Laughter.]

It is very unfair, I can tell you, because in the fight to fulfill these needs, I couldn't have a chairman with a better steel rod for a spine than Mark Hatfield. He is really a hell of a guy.

Senator HATFIELD. Thank you very much. We make a good team.

Senator WEICKER. Bye bye, Ray.

STATEMENT OF JAMES A. SWOMLEY, MANAGING DIRECTOR, AMERICAN LUNG ASSOCIATION

Senator WEICKER. Next we will hear from James A. Swomley, managing director, American Lung Association.

Mr. SWOMLEY. Thank you, Senator Weicker. I appreciate the opportunity to be here today and to first express appreciation to you for your leadership in previous years.

My wife, whom you know also, is here today, and we are both very proud of the work that you have done in terms of the health concerns of the American people.

I represent the American Lung Association, and our medical section, the American Thoracic Society. The American Lung Association is the oldest of America's national voluntary health agencies, and our medical section, the American Thoracic Society, is a unique worldwide organization of physicians and scientists who are concerned with lung disease.

Our annual report, which we have just published is entitled: "The Growing Problem of Lung Disease." Lung diseases include two of the leading causes of death in this country, the fifth and sixth ranking causes of death are exclusively lung diseases, pneumonia and influenza, and chronic obstructive pulmonary disease. It also affects several of the other categories of major lung diseases.

One of the interesting facts about lung disease is that while most diseases are declining as a cause of death in this country, lung disease, in both of these categories that I mentioned, have been increasing and becoming a more serious problem in America.

Lung disease is the No. 1 killer of infants in this country. When we talk about lung disease, we are talking about many, many categories of disease, whether we talk about chronic obstructive pulmonary disease, such as emphysema and chronic bronchitis, whether we talk about asthma, pneumonia, influenza, communicable diseases such as tuberculosis, or some of the growing problems in terms of occupational health problems, toxic chemicals, air pollution, cigarette smoking. So we have a wide range of concerns.

Our association is most concerned with the President's budget because we feel that it will, in some areas, cripple what is being done, and in other areas destroy the initiatives in terms of lung disease.

We have listed in the written testimony that has been presented to your committee seven major areas of concern that relate to the President's budget request. In these few minutes, let me comment on just two of these seven areas.

One is the budget of the National Heart, Lung, and Blood Institute. This is where much of the action is in terms of research related to lung disease, and we feel that in this particular area, the problem is most crucial. The three categories that we have major concerns about include the funding for research projects, the funding for research centers, and the funding for research and development contracts. We have suggested what we feel the appropriate levels of funding are for each of these areas.

I would also like to mention tuberculosis. Our association got its beginning back in 1904 as the National Society for the Study and Prevention of Tuberculosis. This was a time when this was the leading cause of death in America. The death rate from 1904 to 1984 had it persisted at the 1904 level would have claimed 21 million American lives, but because of research and many other factors, instead of killing at that level, 4 million people died from tuberculosis, so 17 million lives were spared because of progress.

Today, although for many tuberculosis may be a forgotten disease, it continues to kill approximately 2,000 Americans each year. We have about 20,000 new tuberculosis cases. Most years, we see a decline in the tuberculosis case rate. When we had refugees coming in in great numbers from Southeast Asia, we saw a change in that trend as new cases were brought in from overseas.

Now, we are afraid that we are again seeing a leveling off because of the AIDS relationship to tuberculosis. So here is another factor, and we would like to particularly call your attention to the fact that the President's budget would eliminate the project grants for tuberculosis completely, and we feel that this would be a great mistake, and we would urge your committee to restore these funds as well as the other categories we have mentioned.

Again, we thank you for your leadership, Senator, and it is a pleasure being here with you today.

PREPARED STATEMENT

Senator WEICKER. Nice to see you again, and thank you for all the good work you are doing with the American Lung Association.

Mr. SWOMLEY. Thank you.

[The statement follows:]

STATEMENT OF JAMES A. SWOMLEY

Mr. Chairman and Members of the Subcommittee, the American Lung Association and the American Thoracic Society, ALA's medical section, thank you for this opportunity to comment on the health and biomedical research programs in the FY 87 budget which are of particular concern to our lay volunteers, scientists, and health care professionals. I am James Swomley, Managing Director of the American Lung Assoication.

ALA/ATS will focus its concerns on those programs relative to the prevention and control of lung disease. These diseases constitute a devastating and growing health problem in the United States. Lung diseases range from the chronic and often fatal diseases of the newborn, to serious infectious diseases, to those related to environmental exposures--workplace and ambient air, and to diseases attributable to cigarette smoking--the leading cause of preventable death. When lung cancer and emphysema are included, lung diseases altogether rank third among the leading causes of death and sixth among the conditions responsible for premature retirement due to disabiltiy. COPD--Chronic Obstructive Pulmonary Disease--is the most rapidly increasing of the 10 leading causes of death. The direct and indirect costs of lung diseases will be a staggering $36.5 billion in 1985.

Grim as this statistical picture appears, it is not hopeless. Federal programs of disease prevention and health promotion, biomedical research, environmental and occupational health hazard control, and professional education and training have greatly improved the detection and treatment of many of these diseases. Furthermore, there are many exciting advances at the threshhold of translation into new diagnositic modalities.

The ALA/ATS has reviewed the lung related research, training, and demonstration programs for the National Heart, Lung and Blood Institute as well as for other institutes and agencies conducting activities related to the prevention and control of lung disease. Our recommendations are summarized below. The recommendations represent the best estimate, by physicians and scientists of the ALA/ATS, of the adequate resources necessary to continue these programs at the level of priority indicated by the magnitude of the lung disease problem.

Summary: FY 87 Health Appropriations Recommendations

National Heart, Lung and Blood Institute	$924.3 M
National Institute for Allergy and Infectious Diseases	$417.6 M
National Institute for Environmental Health Sciences	$212.8 M
National Institute for Occupational Safety and Health	$ 64.7 M
Tuberculosis Project Grants (Centers for Disease Control)	$ 10.0 M
Office of Smoking and Health	$ 5.0 M
Office of Health Promotion	$ 5.0 M

Our remaining comments, Mr. Chairman, will explore the resource needs of the National Institutes of Health, specifically the National Heart, Lung and Blood Institute. Additional comments will focus on the proposal to once again eliminate the program for Tuberculosis Project Grants administered by the Centers for Disease Control.

THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE

The National Institutes of Health represent the largest source of funding for lung related research in the U.S. This research progarm--principally within the National Heart, Lung and Blood Institute--has contributed significantly to the remarkable progress made in the past decade towards unmasking the basic physiological events underlying the development of lung diseases, and devising treatments and preventive strategies for these diseases. Yet the President has proposed a budget of only $785.7 million for NHLBI, an 8.6% reduction from the FY 86 appropriated level.

The NHLBI research portfolio supports several research mechanisms. **Research Projects** support basic research and small-scale clinical studies. **Research Centers** are used to support multi-disciplinary research focused on major disease entities and to ensure that fundamental research outcomes are rapidly made available to the clinical arena. **Research and Development Contracts** are the best mechanism to support clinical trials and other population-based studies. The President's proposed budget would impact each of these mechanisms.

The Project Grant continues to be the keystone of the NHLBI research program. The largest portion of the research portfolio is dedicated to this mechanism. The President's proposed FY 87 budget contains only modest changes in this function--a reduction from the FY 86 appropriated level of 2704 competing and noncompeting grants to 2605 competing and noncompeting grants. This limited reduction in numbers of grants is in part due to the specific language in the FY 86 appropriations bill. However, the funding levels have been reduced by 7% which will require that noncompeting grants be negotiated downward an average of 11.3%. Reduction in the funding level of indivudual grants will have a significant impact on the ability of researchers to accomplish the goals set out in their grants. A reduction of this level may impair the scientific integrity of grants and in some cases, may make completion impossible.

A further problem related to the NHLBI budget is the growing imbalance in the research program. The distribution of funds among research mechanisms has markedly changed in recent years to the point where the Institute is no longer able to maintain a balanced program. For example, **Projects** received 58.3% of the total funds in 1980, growing to 71.9% in the President's proposed FY 87 budget. **Centers** were funded at 13.6% of the total NHLBI funds in 1980, declining to 10.9% in the President's proposed FY 87 budget. **Contracts** were funded at 17.3% in 1980, declining to 7.5% in the President's proposed FY 87 budget. As a consequesnce of these changes in distribution, the Centers and Contracts mechanisms may be severely compromised. A review of the President's proposed budget for these mechanisms demonstates this clearly.

The NHLBI supports 60 Specialized Centers of Research--SCORs. Of the 60 Centers provided for in the budget, 24 are scheduled for competitive renewal in FY 87. While the number of Centers to be funded remains stable, the funding level is reduced by 13% from the FY 86 appropriated levels. Further confounding this budgetary dilemma is the fact that Center awards are for a five-year period. During the renewal process significant budget growth is anticipated to counter previous inflation and to allow for adequate resources throughout the period of the award. The President's budget allows for $75.8M for this function. In actuality, the level of support should be, at a minimun, $93M to allow adequate budget resources and enable the Centers to achieve their research objectives.

The SCOR program is a unique research mechanism which includes both basic and clinical research emphasis to ensure that advances in the basic sciences are quickly translated into applications at the clinical level. This research mechanism direclty benefits patient and public health. A major reduction of this research mechanism will result in the slowdown of direct application of research findings and subsequent benefits to patients.

The NHLBI also supports a number of Clinical Trials through the Contracts mechanism. In the Division of Lung Disease, a major trial has been initiated to study Chronic Obstrucitve Pulmonary Disease--COPD, the most rapidly increasing of the 10 leading causes of death in the U.S. This trial represents an 8-year obligation by the NHLBI to determine if those persons considered to be most susceptible to the development of COPD can avoid these problems if they stop smoking, and to see if progression of their disease can be slowed by the use of certain bronchodilator medications.

The President's proposed budget shows a 3% reduction in funding from the FY 86 appropriated levels for this mechanism. This apparently modest cut is misleading. For example, during the first year of a trial, moderate costs are encountered as the study design and research protocol are developed. During the second year, major budgetary growth is necessary to absorb the costs related to equipment acquisition and patient recruitment--critical activities the COPD Trial is just entering. A level of funding for the Contracts mechanism of $75M would allow continuation of the current level of support. This amount, however, would still cause significant limitations in research activity.

A final issue with direct impact on the NHLBI research program is the lack of flexibility in program management. Since August 1985, the funds apportioned to the Institute are specified for each mechanism of support, with further specification of non-competing and new or competing awards. The inflexibility created by this process seriously limits the ability of NHLBI to manage programs to meet the changing research needs and priorities--a role the peer review process and Advisory Councils and Research Committees have addressed in the past. The process of requesting to reprogram the budget is a very slow and restricted one and as a consequence, some opportunities are missed. Further, the imbalance among support mechanisms is accentuated.

TUBERCULOSIS PROJECT GRANTS

Originally organized to combat tuberculosis, ALA/ATS continues its commitment to the eradication of TB. ALA is again surprised by the shortsighted action of the Administration to eliminate funding for this program. First authorized in 1982, TB Project Grants, administered by the Centers for Disease Control, provide cooperative agreements for TB control activities to state and local health departments in high incidence areas.

In 1980, 28,000 cases of TB were reported in the U.S., a 0.6% increase over 1979. Such an increase had been seen only twice in the past 25 years. A major contributing factor was the large number of cases diagnosed in the Indochinese refugee population. In 1981, the rate declined 6% to 27,373 cases and in 1982 a further decline of 7% was noted. This decline continued in 1983 and 1984 with 5.7% and 7.8% decreases respectively; decreases, noted by ALA/ATS, anticipated with an adequately functioning TB control program.

In 1985 it appears that once again there will be no decline in TB morbidity. Provisional data indicate that, if seen, the decline will be as little as 2%. Speculation is that once the data are finalized, this very small decline will disappear. In addition to the problems of drug resistant TB, TB among immigrants and refugees, and TB in children, new problems have emerged related to an increasing incidence of infection in those with the AIDS virus, and outbreaks among the homeless.

The program of TB Project Grants should be intensified in light of the current and emerging transmission problems rather than eliminated. Moreover, the program has undoubtedly saved third-party-payers millions of dollars in hospitalization costs. For example, Connecticut, Los Angeles, and Massachusetts report annual savings of $81,000, $500,000, and $250,000 respectively through the use of outreach workers and directly observed therapy.

CONCLUSION

The federal government provides a significant source of funding to a wide range of programs direclty impacting the prevention and control of lung disease. In the absence of adequate federal support, neither state nor local governments, nor the private sector are financially capable of continuing this level of programing. Furthermore, while it may appear tempting to assume that the private sector could be encouraged to accept some responsibility for support, this support might come at the high price of limited investigation or reversal of research direction.

Reductions to the extent proposed by the President will lead to the dismantling of the federal research program. This reduction would occur at a time when national and international industries are developing around our new biomedical technologies, negatively impacting on this economic growth. Great advances made over the last twenty years are now being capitalized upon in cell biology, molecular biology, and other biosciences. Past effort has clearly placed the U.S. in the forefront internationally and this level of effort must continue if our federal research program and supporting industries are to remain competitive.

The health and biomedical research programs of the federal government give strength and leadership to our entire health care system. We are now at the threshhold of remarkable breakthroughs in biomedical research which will lead to significant improvement in the health of the nation. Thus, now more than ever, vigorous support and adequate resources are essential.

STATEMENT OF ANTHONY DeMARIA, M.D., CHAIRMAN, GOVERNMENT RELATIONS, AMERICAN COLLEGE OF CARDIOLOGY

Senator WEICKER. Next we have Dr. Anthony DeMaria, chairman of government relations, American College of Cardiology.

Dr. DEMARIA. Senator Weicker, I am Anthony DeMaria, professor of medicine and chief of the Cardiovascular Division at the University of Kentucky, and vice president of the American College of Cardiology. I represent that organization which has about 14,000 members, and is a specialty society in cardiology.

We presented our written statements and rather than read those, I thought I would just bring up a couple of pertinent points that we are very concerned with.

We do, of course, support the activities of the NIH, and we are concerned about the funding and appropriation of the NLHBI in particular. I began by saying that we recognize that these are difficult times financially, and we thank you very much for your leadership and support in the fight to maintain funding of cardiovascular research.

From the standpoint of the magnitude of the problem, we come here relatively flush with victory. The rate of mortality of cardiovascular diseases is 60 percent at the current time of what it was in 1964. As a matter of fact, the rate of decline in mortality of cardiovascular diseases has been three times greater than that of other diseases. Because of your support, we have done extremely well in the past. The problem, however, is still enormous in that cardiovascular diseases account for nearly as many deaths as all other forms of disease put together.

For example, we have 58 million people with hypertension; 6 million with coronary disease. The President's proposed budget represents something of a regrettable retreat from previous levels of support for cardiovascular research, and that is really one of the points that we would like to address.

There are a couple of specific issues we have concerns about. One is in the support of research training. I think, as an academic physician, this is something that really is particularly pertinent. I think that we are in potential danger of sacrificing our future.

The President's budget would represent a 12.5-percent reduction from 1986 levels of research training support, nearly 5 percent withdrawal of funds. If we don't train future generations of cardiovascular investigators, then we will just never solve the problems in the future.

Given the difficulties involved in a career with cardiovascular investigation, particularly for physicians, I think that it is very important to support that.

Our second area of concern is with support of the score programs in specialized centers of research which not only deal with new basic knowledge, but with the translation of that basic knowledge of clinical care. That is also proposed for about a 12-percent reduction.

After discussing and deliberating about this, we have come up with some recommendations. We think that it is reasonable, given the tenor of the times, to ask that the NHLBI be supported at their 1986 level, which was $848.6 million, with a 4-percent increase for inflation. That will not provide any significant new funds, but will at least hold things at their current level.

The second area of concern we have is how these funds are spent, and the flexibility that the NHLBI would have in spending these funds. Traditionally, the program has been balanced. It has consisted of investigator originated research as well R&D contracts, and program project grants. OMB would propose specific regulations for funding for each category. We would like to propose that you and your committee see to it that certain minimum flexibility remains in the program so that research initiative may be maintained. We recommend the range of support which would be 12 percent for research centers, 8 percent for R&D contracts, and 11 percent for other activities such as research training awards.

Again, thank you very much for your support in the past, and I will be happy to support any questions.

PREPARED STATEMENT

Senator WEICKER. I have none. Thank you very much for your testimony, Dr. DeMaria.

[The statement follows:]

STATEMENT OF ANTHONY N. DEMARIA

Mr. Chairman, and members of the Subcommittee, I am Dr. Anthony N. DeMaria, Professor of Medicine and Chief of the Cardiovascular Division at the University of Kentucky. I am pleased to participate in today's deliberations as representative of the American College of Cardiology, of which I am Vice President and Chairman of the Government Relations Committee. The College is a 14,000 member medical specialty society dedicated to the prevention and optimum treatment of cardiovascular disease. As such, the College is vitally interested in the research and training components of the National Heart, Lung, and Blood Institute (NHLBI) and in the continued scientific progress of this vital Institute.

Mr. Chairman, allow me to begin by expressing the deep gratitude of the scientific research community for your own leadership and for the dedication of the Subcommittee in supporting the National Institutes of Health in general and the NHLBI in particular. We recognize that your vigorous backing during these difficult times has been an inspiration to all of us who look to the NIH for support and leadership.

Enormous progress has been made in the last twenty years in the effort to eradicate heart disease, but much remains to be done. The death rate for coronary heart disease in 1984 was only 60% of what it was in 1964. Yet, in 1984, cardiovascular diseases continue to cause nearly half of all deaths. The decline in deaths related to cardiovascular disease has been more than three times faster than the decline for all other causes of death combined. Still, some 58 million people have hypertension, 6 million have coronary heart disease, and 2 million have cerebrovascular disease. There were 740,000 fewer deaths in 1984 from heart disease than would have occured had the death rate not declined so dramatically. Yet, in 1983, the economic cost of cardiovascular disease remained an estimated $102 billion: $48 billion in direct health expenditures, $13 billion in indirect cost of morbidity, and $41 billion in indirect cost of mortality.

The President's Budget

The President's FY 1987 budget for NHLBI represents a significant and regrettable retreat from current support levels in a number of critical areas. Support for research training is marked for a 12.2% decrease in the coming fiscal year. This is a cut of almost $5 million in a budget of some $40 million. Although there may be adequate or even excessive numbers of practitioners in many areas of medicine, this is almost certainly not true in the research component. A recent survey of cardiology training directors conducted by the American College of Cardiology revealed that 80% think that additional numbers of cardiologists are needed in research and only 1% supported a decrease in the number of research cardiologists. Physician researchers are pivotal to the success of our entire cardiovascular research effort, since they are able to give clinical relevance to basic discoveries and many are directly involved in patient-oriented research.

Despite the pressing need for new researchers, the proposed budget would deflate this effort enormously. We estimate that if the President's budget were approved, at least 87 meritorious National Research Service Awards will go unfunded this year (if the rescission were approved). Next fiscal year, the number of unfunded meritorious applications would increase to 164. The long range cost to the American health care system of discouraging this contingent of talented researchers from pursuing their goals would be extremely unfortunate and far-reaching. We would feel its effects well into the next century.

Another area singled out for particularly large cuts in the President's budget is the Specialized Centers of Research (SCOR) effort. SCORs were instituted to advance basic knowledge and to generate the most effective techniques and methods of clinical management and prevention in the areas of arteriosclerosis, hypertension, ischemic or coronary heart disease, thrombosis and blood resources. Some 1200 research scientists receive some support under the SCOR program.

The Administration proposal for FY 1987 would reduce funding by more than $7 million for SCORs. This would amount to an 8.5% cut. A reduction of this magnitude would have severe consequences for ongoing SCOR intitiatives including key research on arteriosclerosis and almost the entire clinical research program in children's lung diseases.

Many other research initiatives will be deferred or delayed if the President's 1987 budget is approved. These include the following:

o Studies of the impact of fatty acids in diet on the incidence of thrombosis and coronary heart disease.

o Important research on the artificial heart and circulatory assist devices.

o Studies of the cause and effect of blood pressure elevation in pregnancy. Hypertension in pregnancy is associated with 25,000 stillbirths and neonatal deaths, and 300 maternal deaths each year. Important studies are planned of the etiology and pathophysiology of the condition, characterizing the populations at risk, and studying the effects of antihypertensive medications upon mother and fetus.

o Important studies of laser applications in cardiovascular treatment. The application of promising laser technology to the diagnosis and treatment of heart disease is in its infancy. Research is needed on the ability of laser technology to perform angioplasty, arterial welding, ablation of heart muscle for the control of certain arrhythmias, and other areas. Questions about the optimal amount of energy needed to perform these various procedures must be answered before clinical applications can go forward.

o Studies of minimally invasive techniques to detect coronary artery lesions. Detecting, locating, and measuring the degree of narrowing in coronary arteries is essential in the clinical management of persons with coronary heart disease. Presently, this measurement is done by way of coronary angiography which employs injections into the major coronary arteries and the use of x-rays. The replacement of this procedure with a non-invasive one is a high priority for the cardiovascular community.

These are just a few of the many areas of research which will suffer in the proposed budget. Great strides in the diagnosis and care of cardiovascular disease have been made, but important breakthroughs are still to come. We urge the Congress to continue to provide support for the efforts outlined above and not to jeopardize cardiovascular research and the future health of our people. Instead, we ask for a maintenance budget amounting to last year's appropriated level plus four percent for inflation in all NHLBI program areas. We also ask that the Subcommittee continue to resist efforts to rescind appropriated funds which, as an investigator, I can assure you is extremely damaging to carefully budgeted research projects.

Mission of NHLBI

In addition to the overall budget level, the ACC would like to address another issue which has become of vital importance to the mission of the Institute. Of course, the cornerstone of the Institute's portfolio has been the investigator-initiated grant, and this program has grown from 58% of the Institute's budget in 1980 to over 70% of the current extramural research budget. However, one of the key aspects in the remarkable success of the NHLBI program has been a versatile and balanced approach to research funding, which has allowed the Institute's Advisory Committees and the Advisory Council to direct a portion of the budget toward research in particular vital areas. Thus, several support mechanisms in addition to the investigator initiated grants have been extremely successful, including the specialized centers, which carry out a large proportion of the clinical research, and the R and D contract mechanism through which clinical trials of new drugs or new procedures such as coronary angioplasty, as well as much work on the artificial heart can be funded.

A very serious problem with the use of these funding mechanisms has arisen because of the current practice of rigid specification by OMB of funding for each category. Therefore, we strongly urge that the Congressional budget allow some flexibility to the Institute staff working with its advisory groups. We recommend that a range of funding be allowed within the NHLBI appropriations for the major support mechanisms as follows:

Research centers: up to 12%
R and D contracts: up to 8%
Other (including training): up to 11%

This would allow maintenance of a minimum of 69% for research project grants. Such a range specification would provide the Institute with the extremely important ability to take advantage of research opportunities by reprogramming resources up to a specified percentage, and thereby to maintain its momentum in clinical research and training, as well as in fundamental research.

Mr. Chairman and members of the Subcommittee, it is indeed a privilege to meet with you today on behalf of the American College of Cardiology. We look forward to continuing to work with the Subcommittee and its fine staff in our common effort to help those who are afflicted with heart disease, our nation's number one killer.

STATEMENT OF KENNETH SHINE, M.D., PRESIDENT-ELECT, AMERICAN HEART ASSOCIATION

Senator WEICKER. Our next witness is Kenneth Shine, president-elect of the American Heart Association.

Dr. SHINE. Senator, I am Dr. Ken Shine, dean-designate of the UCLA School of Medicine, and president-elect of the American Heart Association.

Thank you for allowing us to come and also for your continued support of biomedical research in our attempts to decrease deaths and disability from heart disease.

Tony DeMaria has pointed out to you that although heart disease continues to be the most important cause of death in our society, we have had a significant decrease on that death and disability, a 39-percent decrease between 1964 and 1984.

We estimate at the present time that the economic costs of heart disease are about $102 billion a year. I would like to point out that if that decrease in death and disability had not occurred, if we were still looking at the same levels of heart disease as we observed in 1964, that health care bill would be about $170 billion. The $68 billion difference is what I would call the savings of scientific success, that is, they represent the chest pain that hasn't been felt, the heart attacks that have not occurred, the young and middle-age individuals who haven't dropped dead from heart disease. I believe that this is largely the result of a combination of good research and efforts at prevention.

The heart association for some 40 years has been in the vanguard of trying to alter dietary behavior, reduce high blood pressure, smoking cessation, and its success in this regard has been based on the fact that there has been good science to support what it does. For that reason, it contributes substantial amounts of its own budget to research, but we are increasingly concerned that the decisions made by Federal officials, solely for fiscal years, in the present may have a detrimental long-term impact on the ability of us to do research, particularly in the National Heart, Lung and Blood Institute [NHLBI].

The President's budget includes only $785.7 million, an overall reduction for the NHLBI of 4.5 percent from fiscal year 1986 adjusted level of $822.3 million. We believe that the impact of that budget would be devastating.

Only 802 new and competing research grants could be funded as compared to 886 in 1986. The centers program would be funded at $75.7 million, while the institute estimates that it would need some $93 million to maintain this activity. We support Tony's comments with regard to scores and other center proposals.

The dollar level and number of research career awards would be held constant at 364 and $21 million, but the number of full-time training positions in heart and lung would be reduced from 1,627 to 1,500, a decrease of 127. Those are the new minds, the new ideas, the new trainees, the new researchers that Tony was referring to and that we believe are very important for the future of research.

Contracts would be funded at $51.9 million, which is far below the level required to maintain current and projected contract requirements.

Construction and renovation grants would be eliminated. The intramural program would be reduced by as much as 25 percent under that budget.

The heart association believes that the programs of the Institute have been very successful in the fight against heart disease, but they have been successful while maintaining a program balance. The administration's new allocation and apportionment procedures are threatening the success of this time tested approach to research.

It is our concern that a continuous focus on a number of grants only to be funded by the Institute may also jeopardize the success of other program mechanisms. The Institute is by nature a clinical institute. To maintain program balance requires basic research, but also clinical aspects, and we believe that the Institute and its advisory council must be given the flexibility to do that job.

We believe that the President's budget request is inadequate, and we endorse the ad hoc group for medical research's recommendation of an NIH budget of $6.1 billion, a 10-percent increase over fiscal year 1986. This level of increase is consistent with those proposed by the President for other Federal research and development activities.

We, therefore, recommend an increase of 10.6 percent for fiscal year 1987 appropriations of $950.3 million for the Heart, Lung, and Blood Institute. This funding level has also been recommended by the advisory council of the Institute as the minimum amount needed to maintain its programs.

We also urge that the institutional basic science research grants which help so many young cardiovascular investigators be preserved. It is crucial, flexible money for the fight against cardiovascular disease.

Once again, we thank you for your efforts, your insight, and your eloquent support of biomedical research in the fight against heart disease.

PREPARED STATEMENT

Senator WEICKER. Dr. Shine, thank you very much for your testimony, both here today and earlier. I think that you have put those figures in the proper focus. We will see what we can do.

Dr. SHINE. Thank you.

[The statement follows:]

STATEMENT OF KENNETH SHINE

I am Dr. Kenneth Shine, Dean-Designate of the UCLA School of Medicine, and President-elect of the American Heart Association (AHA). The AHA is the only voluntary agency in the United States devoting all of its human and financial resources to one goal: the reduction of premature death and disability caused by heart attacks, stroke and other blood vessel diseases. In accomplishing this goal, we work in partnership with several Federal research, education and prevention programs whose goals are similar in nature. Since 1948, the AHA and the National Heart, Lung and Blood Institute (NHLBI) have been active partners in the battle against cardiovascular disease -- this Nation's leading cause of death. I am pleased to appear before your Subcommittee today to provide you with our comments and funding recommendations for the NHLBI.

Cardiovascular disease is responsible for almost one million deaths each year. Heart disease, stroke and related disorders account for almost as many deaths as all other causes of death (cancer, accidents, etc.) combined. In 1986, the total economic costs associated with cardiovascular disease are estimated to be over $102 billion in direct medical expenses and lost output due to disability and death. However, there is encouraging evidence that we are making progress against these diseases. Between 1964 and 1984 the death rate for all cardiovascular disease declined by 39 percent.

Throughout our 37-year partnership the research, training, education and community service programs of both the AHA and the NHLBI have had a significant impact on diseases of the heart and circulatory system. While AHA continues to dedicate an increasing amount of its budgetary resources to cardiovascular research, we are hopeful that the NHLBI will be able to continue to take advantage of current and future research opportunities in the cardiovascular field. We are becoming increasingly concerned that decisions made by Federal officials solely for fiscal reasons in the present may have a detrimental long-term impact on the ability of the Institute to make more critical decisions for appropriate scientific reasons.

In addition to the Gramm-Rudman funding cuts, we are very concerned with additional reductions that appear on the horizon. Although we have made great progress in the fight against cardiovascular disease, we must not become complacent because of past accomplishments. Currently it is estimated that over 63.6 million Americans have one or more forms of cardiovascular disease -- high blood pressure afflicts an estimated 57.7 million individuals; 4.7 million have coronary artery disease; 2.1 million suffer from rheumatic heart disease; and over 1.9 million Americans have suffered a stroke. In addition, there is growing evidence that shows the incidence of heart attack may no longer be on the decline. In order to continue to have an impact on the downward trend in mortality due to cardiovascular diseases, the NHLBI has planned to undertake several exciting new activities in FY 1987, including the following:

- continuation of a clinical trial to assess whether intravenous injections of a thrombolytic agent during the early hours of an evolving myocardial infarction is efficacious. This drug therapy will be used in combination with a procedure known as PTCA or balloon angioplasty.
- a study of the mechanisms that underlie normal cardiac morphogenisis in order to increase understanding of the etiology and pathogenisis of congenital heart failures.
- a clinical trial to assess behavioral and lifestyle interventions contributing to an individual's successful adjustment after coronary artery bypass graft (CABG) surgery and to identify operative, clinical and other factors that may predict early and late graft narrowing and occlusion after surgery.
- an investigation into the feasiblity, acceptability, efficacy and safety of dietary intervention in children with elevated LDL-cholesterol levels. Potential adverse psychological responses to diagnostic labeling and dietary intervention will also be evaluated.

These are but a few examples of NHLBI's planned program initiatives for FY 1987. We are very concerned that these and others, particularly the planned clinical trials, will not be allowed to proceed due to a lack of necessary funds.

The President's budget includes only $785.7 million, an overall reduction for NHLBI of 4.5 percent from the FY 1986 adjusted appropriation level of $822.3 million. The programmatic impact of the President's proposed 1987 budget on NHLBI will be devastating. The Institute will be able to fund only 802 new and competing research project grants as compared with the 886 grants that it funded in 1986; and funding for noncompeting research projects will have to be negotiated downward an average of 11.5 percent.

The Institute's research centers programs would have to be reduced significantly under by the President's proposed budget. In 1986, the Institute allocated $82.8 million for its research centers program. It is estimated that in order to continue this same level of activity in 1987, the Institute would need approximately $93 million. The President's budget, although it calls for the same number of centers to be funded, provides only $75.7 million for this purpose. Research center projects serve as a highly effective means of concentrating resources, facilities and research personnel on high priority research areas. We believe it it highly unwise to underfund such programs.

Under the President's budget the dollar level and number of research career awards will be held constant -- 364 awards and $21.9 million. In addition, the number of full-time training positions will have to be reduced from 1,627 to 1,500, a decrease of 127 positions.

While the amount provided by the President's budget for research contracts, $51.9 million, is a slight increase over the FY 1986 level (approximately $1.1 million), it is far below the level required to maintain current and projected contract activities for FY 1987-- approximately $75 million. Several research contract programs would have to be delayed or eliminated should they be funded at the level proposed by the President. When one takes into account the amount of time and resources that would be lost due to a cancellation of currently-funded contracts, it would amount to a significant waste of biomedical research dollars.

The President's budget completely eliminates NHLBI's funding for construction grants. We believe that this funding, at a minimum, should continue at its FY 1986 level of $3.2 million. And finally, the intramural research program of the Institute will have to reduce operating costs by as much as 25 percent under the President's proposed budget.

In order to illustrate the true impact of these proposed budget reductions we would like to highlight one important program area -- cholesterol research and education -- at NHLBI. For over 25 years, the AHA has advised physicians and the public about the merits of a low-fat, low-cholesterol diet as a means of reducing the risk of coronary heart disease. We are very excited about NHLBI's new National Cholesterol Education Program (NCEP) which is modeled after its highly successful National Hypertension Education Program. The area of cholesterol research and education is a prime example of an area where AHA and the NHLBI can work in a cooperative manner to tackle an important public health problem.

However, several program activities in this area are threatened by budget reductions in FY's 1986 and 1987. In the area of cholesterol research, over $4 million in grants has been approved in FY 1986 but will not be funded as a result of budget reductions. One important workshop on the treatment of severe hypercholesterolemia has been cancelled, and another on the impact of dietary cholesterol on plasma lippoproteins and atherogenisis is in jeopardy. Also in jeopardy is the Institute's ability to assist the Centers for Disease Control in the implementation of the Cholesterol Standardization Program. This effort is crucial to taking steps to make clinical laboratories more consistent and accurate in the measurement of cholesterol levels and represents one of the early priority activities of the National Cholesterol Education Program.

With regard to planned cholesterol research activities in FY 1987, proposed budget reductions will endanger several promising areas of investigation including the use of non-human primates to obtain a better understanding of the relationship of cholesterol and atherosclerosis; a clinical trial to study the effect of postmenopausal estrogen use on coronary heart disease in women; and research into the effects of dietary factors on lippoprotein structure and metabolism. In addition, a number of planned cholesterol workshops may not be held due to a shortage of funds.

In the areas of cholesterol education, in FY 1986 the Institute's cholesterol-related publications have been reduced significantly in number. In addition, the Institute has had to reduce its exhibiting schedule and its ability to respond to requests for spokespersons to talk about the NCEP at various conferences and meetings because of a reduced travel budget. A workshop to stimulate both intervention and research related to cardiovascular risk reduction at the worksite may not be held as well. In FY 1987, the Institute will have to reduce in scope some major activities that are already underway such as the major support services contract for the NCEP and the contract to develop broadcast and print materials to carry the Program's message to the public.

The AHA believes that the Institute's efforts in cholesterol and education research should not be sidetracked or slowed at this critical time. Any reduction in effort as a result of a lack of funding in FY's 1986 and 1987 is most unfortunate and would ultimately lead to increased health care costs for the Nation.

AHA believes that the programs of the NHLBI have been highly successful in the battle against cardiovascular disease because of the valuable principle which guides the Institute -- maintaining research program balance. While the cornerstone of its program is basic research, the Institute's staff, Advisory Council and the scientific community over the years have also stressed the importance of other program mechanisms such as clinical trials, population studies, specialized centers of research (SCORS), national research and demonstration centers, research career and training awards and development contracts. This balanced program approach has enhanced the NHLBI's reputation as a world-wide leader in cardiovascular research.

At this time we would like to highlight some of our concerns regarding the increasing invovlement of the Office of Management and Budget in the program activities of the National Institutes of Health. As we understand the situation, as of August, 1985 the OMB instituted a new mechanism for apportioning funds to the National Institutes of Health (NIH) which, in turn, required the Office of the Director of NIH to adjust its allotment procedure to the individual institutes. Prior to August of 1985, OMB apportioned funds to the NIH by institute total and then the Director of NIH alloted funds to the individual institutes with only two categories earmarked -- SBIR and consulting services. Allocation among programs of the remaining, and largest, part of the institutes' budgets was left to the individual institutes. Now the institutes receive their allotments for the NIH director in thirteen categories, each broken down by number of awards and dollar amount as determined by OMB. We do not beleive that the OMB staff has the scientific expertise and outlook to be making these kinds of decisions; these decisions should be made by the individual institutes and their advisory councils with input from the biomedical research community.

The Administration's new allocation and apportionment procedures are threatening the success of NHLBI's time-tested approach to research. In addition, it is our concern that a continual focus on the number of grants to be funded by the Institute may also jeopardize the success of other program mechanisms. For example, in 1980, 58 percent of NHLBI's extramural research budget went towards research grants, 14 percent went towards research centers, and 17 percent went towards clinical trials. In 1986, these same programs mechanisms received 70.4 percent, 11.7 percent and 7 percent respectively of NHLBI's extramural research budget. This is a very disturbing trend indeed. The NHLBI is, by nature of the disease categories under its research mandate, a "clinical institute." In order to maintain program balance that addresses basic research needs as well as the clinical aspects of heart, lung and blood diseases, the Institute and its Advisory Council must be given the proper amount of flexibility to allocate resources where they are most needed and where they will bring about the best results.

The AHA believes that the President's budget request for the National Institutes of Health is highly inadequate. Adequate funding of research is not only an investment in this Nation's future health but produces significant savings in health care costs as well. Specific examples of advances in the cardiovascular field which have led to significant cost savings are advances in coronary artery surgery research and percutaneous transluminal coronary angioplasty (PTCA) which have resulted in annual net savings to the Nation of over $654 million.

We endorse the Ad Hoc Group for Medical Research's funding recommendation for NIH of $6.1 billion, a 10.6 percent increase over the FY 1986 appropriations level. This level of increase is consistent with those proposed by the President for other Federal research and development (R&D) activities. A 10.6 percent increase for NIH would allow for modest growth over its current services budget level and would allow for:

- competing and noncompeting research grants to be funded at full study section-recommended levels;
- some growth in research careers awards and sufficient funding to raise the current level of research trainees to that recommended by the National Academy of Sciences (11,500 trainees);
- urgently needed upgrading and renovation of primate centers and outmoded and inefficient research laboratories; and
- a slight increase in the number of research centers.

We therefore recommend an increase of 10.6 percent, or an FY 1987 appropriation of $950.3 million, for the National Heart Lung and Blood Institute. This level of funding has also been recommended by the NHLBI Advisory Council as the minimum amount needed for NHLBI to maintain its current research programs.

STATEMENT OF JAMES E. DALEN, M.D., PRESIDENT, AMERICAN COLLEGE OF CHEST PHYSICIANS, UNIVERSITY OF MASSACHUSETTS SCHOOL OF MEDICINE

Senator WEICKER. Next we have Dr. James Dalen, president of the American College of Chest Physicians. Dr. Dalen is from the University of Massachusetts School of Medicine.

Dr. DALEN. Thank you, Senator Weicker.

I represent the American College of Chest Physicians, a professional medical society of more than 12,000 physicians, scientists, and educators who specialize in diseases of the heart, lungs, and circulatory system.

The American College of Chest Physicians enthusiastically supports the activities of the NIH, particularly those of the NHLBI and NIAID. We unequivocally support the Institutes' commitment to support the entire spectrum of research, both basic and applied, for treatment and for prevention.

The investment in these areas over the past few years has been extremely productive. Under the able leadership of Dr. Claude Lenfant, tremendous strides continue to be made in combating cardiovascular and cardiopulmonary disease. Our recommendations are aimed at maintaining that momentum.

Although we recognize the strains that have been placed on the Federal budget in recent years, the fact that diseases of the heart and lungs continue to pose the most serious threat to our Nation's health does not escape us. Desirability of exercising fiscal austerity should not be lost to this fact.

Cardiovascular diseases affect more than 60 million people and cause 1 million deaths each year. It is, therefore, imperative that the NHLBI be afforded sufficient resources to continue its efforts to combat the full spectrum of cardiovascular diseases. The battle against those diseases is far from over.

NHLBI's concerns are far broader than cardiovascular disease. The NHLBI has achieved an excellent strategy to meet the serious health problems imposed by lung diseases; 18 million Americans suffer from chronic lung disease. Moreover lung disease accounts for 47 percent of all deaths under 1 year of age. Thus, diseases of the lungs are the sixth leading cause of death in the United States.

Some of the major NHLBI clinical trials funded in the midseventies are still ongoing and still need support. The National Institute of Allergy and Infectious Diseases sponsors important research projects which have broad implications in the respiratory field.

So we continue to support these research efforts that are aimed at the ultimate approach to cost saving which, of course, is prevention. On behalf of the ACCP's membership, I would like to thank you for giving us the opportunity to present our views.

Thank you very much.

PREPARED STATEMENT

Senator WEICKER. Thank you very much for taking the time to appear before the subcommittee. Thank you, Dr. Dalen.

[The statement follows:]

STATEMENT OF JAMES E. DALEN

I am Dr. James Dalen, President of the American College of Chest Physicians. I am also Professor and Chairman of the Department of Medicine, University of Massachusetts Medical School. In addition, I currently serve as Physician-in-Chief, University of Massachusetts Hospital.

On behalf of the American College of Chest Physicians, I am submitting these views for inclusion in the formal hearing record. ACCP is a professional medical specialty society of more than 12,000 physicians, scientists and educators who specialize in diseases of the heart, lungs and circulatory system. The College appreciates this opportunity to offer our views to this Committee on fiscal year 1987 appropriations for the National Heart, Lung and Blood Institute (NHLBI), and the pulmonary activities of the National Institute of Allergy and Infectious Diseases (NIAID).

I would like to preface this statement by emphasizing that ACCP enthusiastically supports the activities of the National Institutes of Health, particularly those of NHLBI and NIAID. We unequivocally support the Institute's commitment to support the entire spectrum of research, both basic and applied; both for treatment and prevention. The investment in these areas over the past year has been extremely productive.

Under the able leadership of Dr. Claude Lenfant, tremendous strides continue to be made in combatting cardiovascular and cardiopulmonary diseases. ACCP's recommendations are aimed at maintaining that momentum. Although we recognize the strains that have been placed on the federal budget in recent years, the fact that diseases of the heart and lungs continue to pose the most serious threat to our nation's health must not escape us. The desirability of exercising fiscal austerity should not be lost to this fact.

Cardiovascular diseases afflict more than 60 million people and cause almost one million deaths each year. Some 58 million persons have hypertension, 6 million have coronary heart disease, and 2 million have cerebrovascular disease. In addition to the untold costs in human suffering, cardiovascular diseases are responsible for a loss of about one hundred billion dollars each year in productivity, wages and costs of medical care.

It is therefore imperative that NHLBI be afforded sufficient resources to continue its efforts to combat the full panoply of cardiovascular diseases: hypertension, cereberal vascular disease, coronary heart disease, arrhythmias, heart failure and shock, congenital and rheumatic heart diseases, cardiomypathies and heart and circulatory system-infection. Although the NHLBI has made considerable progress in the cardiovascular area, the battle against these diseases is far from over.

It is therefore vital that new information be used to gather further insights about cardiovascular diseases. For example, NHLBI supported investigations have elucidated the mechanisms involved in the regulation of levels of blood lipids by receptors on the surface of the liver and other cells that produce particles of low density lipoproteins (LDL) and remove these from the blood stream. The LDL is taken into the cells where it is broken down and yield its cholesterol to serve the cell's needs. When the receptors are defective, LDL cannot be removed normally, and it accumulates to high levels in the blood plasma. The build-up accelerates the atherosclerotic process. Mutations in one of the genes for the receptors can produce heterozygous familial hypercholesterolemia, which is a cause of heart attacks in middle-aged people. Persons who inherit one of these mutant genes for the LDL receptor usually develop heart attacks.

Genetically induced alterations in the LDL receptor have now become the subject of intensive research. Recently, it has become possible to study the molecular genetics of these mutations as a result of the cloning of complementary DNA (cDNA) for the human LDL receptor and the subsequent isolation of genomic clones covering most of the LDL receptor gene. This information would be used to develop insights to the management of the inherited disease, familial hypercholesterolemia, and methods to intervene and control high blood cholesteral.

NHLBI has provided effective leadership in this battle against cardiovascular diseases. Research supported by NHLBI has contributed to such achievements as open heart surgery, cardiovascular and respiratory intensive-care units, diagnostic instruments for use in lung disease, and elimination of hepatitis B as a transfusion hazard. ACCP applauds these achievements. Furthermore, the College supports NHLBI's ongoing basic research efforts involving such areas as: the relationship between behavior and coronary heart disease, the use of immunosuppressive therapy to facilitate heart-lung transplants, to name a few.

NHLBI's concerns are far broader than cardiovascular diseases. NHLBI has also achieved an excellent strategy to meet the serious health problems posed by lung diseases.

Eighteen million Americans suffer from chronic lung diseases. Moreover, lung diseases account for 47 percent of all deaths under one year of age. Thus, diseases of the lung are the sixth leading cause of death in the United States.

In the area of lung disease, the NHLBI focuses on six major areas: the structure and function of the lung; emphysema and chronic bronchitis; pediatric pulmonary diseases; fibrotic and immunological interstitial lung disease; respiratory failure; and pulmonary vascular diseases.

NHLBI's commitment to the study of diseases of the heart and lung is evidenced most clearly in its integrally-linked chain of research methodologies. Comprised of basic research, applied research, clinical investigation and demonstration/health care delivery programs, this system demonstrates the tangible advances which have been made available to the American public through the sponsorship of NHLBI.

In order to meet its mandate, the NHLBI needs to utilize a number of mechanisms to support research. For instance, most investigator initiated research projects support basic research and small scale clinical studies. Research centers are used to support multidisciplinary research focused on major disease entities and to assure that the fundamental research outcomes are rapidly made available to the clinical arena. Research and Development contracts are the best mechanism to support clinical trials and other population-based studies.

Some of the major NHLBI Clinical Trials funded in the mid-1970's that are still ongoing include: studies of Left Ventricular Dysfunction, Systolic Hypertension in the Elderly Program, Cardiac Arrhythmia Pilot Study, Diagnosis of Pulmonary Embolism Trial.

Time does not permit me to discuss the nature of these Clinical Trials in detail. These clinical trials are designed to test, in a carefully controlled setting, the efficiency and safety of preventive and therapeutic regimens before these regimens are introduced into practice. The results of clinical trials are critical. They ensure that unwarranted hospitalizations and premature surgery is avoided, thus helping reduce the costs of health care for our nation. Over the entire century, the gains achieved through expansion in medical research have always far exceeded the level of federal investment.

Given the demonstrated economic soundness of biomedical research activities increased appropriation levels for NIH, and particularly NHLBI, should be a national priority. A modest increase, at a minimum sufficient to counteract the rate of inflation for biomedical research activities, should be sought. The ACCP believes that in order for NHLBI to be able to continue to fulfill its mandate and provide the leadership which is crucial to our national biomedical research effort, an appropriation of 950.3 million is necessary for fiscal year 1987.

The National Institute of Allergy and Infectious Diseases, NIAID, sponsors important research projects which have broad implications in the respiratory field. Studies involving influenza viruses, and respiratory syncytial and parainfluenza viruses, provide important additions to our current level of knowledge of degenerative chronic diseases. Because of the importance of NIAID's research efforts related to viruses, and its study of such diseases as pneumonia and menigitis, ACCP strongly supports increased funding, to a level of 417.6 million, for NIAID.

In sum, the College wishes to express its support for an appropriation level of $6.079 billion for fiscal year 1987 for the National Institutes of Health (NIH). This recommended level of funding would be consistent with our national commitment to biomedical research and would translate into an appropriate, sound, and progressive level of NIH research activity which accurately reflects its vital mandate.

Today, the ACCP continues to lend its support to those research efforts which are aimed at the ultimate approach to cost-saving -- prevention. NIH appropriation levels must be increased to insure that our progress toward that goal is not thwarted. The Federal Government must not turn its back on biomedical advances of the future which could yield billions of dollars in health care savings. Funding levels consistent with the important goals and essential mandate of NIH must be achieved. On behalf of ACCP's membership, I would like to thank you for affording us this opportunity to present our views.

STATEMENT OF KENNETH M. BAKER, M.D., DIRECTOR, CARDIOVASCULAR MEDICINE, GEISINGER MEDICAL CENTER

Senator WEICKER. Our next witness is Dr. Kenneth Baker, director, cardiovascular research, Geisinger Medical Center and Foundation, Danville, PA.

Dr. Baker.

Dr. BAKER. Thank you, Mr. Chairman, and members of the subcommittee: I am Kenneth Baker, director of cardiovascular research at Geisinger Medical Center, which is located in central Pennsylvania.

Each year, more than 36,000 people are hospitalized at Geisinger owned or managed facilities. We are a comprehensive multi-institutional system of health care, and we serve a region encompassing nearly 22,000 square miles.

On behalf of my colleagues at Geisinger, let me state our appreciation for this opportunity to present our views to this committee on fiscal year 1987 appropriations for the National Heart, Lung and Blood Institute.

I would like to preface this statement by emphasizing that Geisinger enthusiastically supports the activities of the National Institutes of Health, and particularly NHLBI and its various programs pertaining to heart research.

We, at Geisinger, unequivocally support the Institute's commitment to fund the entire range of research activities, both basic and applied, both for treatment and for prevention.

It is well-known that cardiovascular disease is prevalent among Americans, both young and old. Cardiovascular diseases afflict more than 60 million people in the United States, and cause almost 1 million deaths each year. Some 58 million persons suffer from hypertension, 6 million from coronary artery disease, and 2 million from cerebral vascular disease.

Cardiovascular diseases are responsible for a loss of about $100 billion each year in productivity, wages, and medical expenses. Given this human suffering and economic consequence, it is imperative that NHLBI resources be expanded so that current initiatives in cardiovascular research can be maintained.

To carry out its program, the institute uses different mechanisms to accomplish specific objectives, including investigator initiated research project grants, the mechanism used to support most of the basic and clinical research that makes up the knowledge acquisition portion of the research continuum.

The institute's specialized centers for research provide a unique environment for concentrating resources, facilities and multidisciplinary expertise to conduct basic and clinical research. These center programs are designed to produce rapid clinical applications of basic science advances, and they continue to be successful.

Given the demonstrated economic soundness of biomedical research activities, increased appropriation levels for NIH, and particularly NHLBI, should be a national priority. Geinsinger believes that in order for NHLBI to be able to continue to fulfill its mandate and provide the leadership which is crucial to our national biomedical research effort, an appropriation of $950.3 million is necessary for fiscal year 1987.

In closing, I would like to quote Dr. Harold Foss, who was the surgeon-in-chief of Geisinger Medical Center from 1915 to 1958. He once said that "Medicine is never static; its leaders can never enjoy the luxury of inertia." These words are as true today as they were back in 1915. Medical research cannot stand still; the Federal Government must not turn its back on biomedical advances of the future, which could yield billions of dollars in health care savings.

On behalf of my colleagues at Geisinger, I thank you for allowing us to present our views.

Senator WEICKER. Thank you, Dr. Baker.

Senator Specter.

Senator SPECTER. Thank you very much, Mr. Chairman.

Dr. Baker, I approve the outstanding work that Geisinger has done. It has been an outstanding institution in so many respects, particularly for serving a very large population in rural Pennsylvania. So frequently, hospitals of this character concentrate themselves in major metropolitan areas. It is a great thing that Geisinger is there to serve the needs of the people in rural Pennsylvania.

Are you able to particularize any breakthroughs which you have experienced at Geisinger in either cancer or cardiovascular research which would be of special concern to this subcommittee?

Dr. BAKER. We are in the process of establishing a new program, a cardiovascular program, in molecular and cellular biology. That program will be up and running during the next year, which will comprise about 15 to 20 senior scientists from around the United States in those areas.

So we are particularly interested in Federal funding as it relates to those basic science programs.

Senator SPECTER. Do you have any expectations of producing very tangible results in terms of some breakthroughs in biomedical research?

Dr. BAKER. Already, with just the early parts of the program, we have had some very tangible breakthroughs.

Senator SPECTER. Dr. Baker, under the National Institutes of Health's fiscal year 1987 budget proposals, I understand that $102 million will be cut from research project grants. What impact, in your judgment, will those cuts have on cancer and cardiovascular research?

Dr. BAKER. Speaking in specifics with regard to the cardiovascular area, I think that it will have a devastating impact. Dr. DeMaria said earlier about increasing the number of RO–1's to 6,000. I think we have had a prevailing attitude for too long of what cuts we can make, rather than moving ahead with what additional things we can fund.

Many of the scores that you look at coming out of the peer review groups should be funded, and are not being funded.

Senator SPECTER. You state a figure as to financial loss. What was the figure you used, $102 billion?

Dr. BAKER. Yes.

Senator SPECTER. What is the source of that projection?

Dr. BAKER. I am not familiar with the source of that, but I can supply it for the record.

Senator SPECTER. If you were to articulate a proposition of cost effectiveness of the research of that $102 billion in offset, would you do that?

Dr. BAKER. As related to cardiovascular disease, I think it has been emphasized earlier, that prevention is a much better mechanism to go about things.

Senator SPECTER. To the extent that you could provide some statistical base on cost effectiveness, I think that it would be helpful. It certainly would be helpful to me, and it would be helpful to the subcommittee. You have a very sympathetic group on this subcommittee. So often, we are faced with the administration's position and that of the Office of Management and Budget, which move to cost effectiveness with some frequency. So to the extent that you could document that, or give us a rationale of cost effectiveness, I think that it would be very helpful. If you could do that in relationship to some specific project that you are undertaking at Geisinger, which you think would be foreclosed with these cuts, that would even be more helpful.

Thank you, Dr. Baker.

Thank you, Mr. Chairman.

PREPARED STATEMENTS

Senator WEICKER. Thank you very much, Dr. Baker. Your statement will be included in the record at this point along with other statements submitted for the record on appropriations for the National Heart, Lung, and Blood Institute.

[The statements follow:]

STATEMENT OF KENNETH M. BAKER

I am Dr. Kenneth Baker, Director, Cardiovascular Research, at the Geisinger Medical Center which is located in Central Pennsylvania. Each year, more than 36,000 people are hospitalized at Geisinger owned or managed hospitals and facilities. More than 500,000 outpatients visited Geisinger physicians last year alone. Geisinger research efforts are an integral part of a comprehensive, multi-institutional system of health care that serves a region encompassing nearly 22,000 square miles.

On behalf of my colleagues at Geisinger, let me state our appreciation of this opportunity to present our views to this Committee on fiscal year 1987 appropriations for the National Heart, Lung and Blood Institute (NHLBI).

I would like to preface this statement by emphasizing that Geisinger enthusiastically supports the activities of the National Institutes of Health, particularly NHLBI and its various programs pertaining to heart research. We at Geisinger unequivocally support the Institute's commitment to fund the entire spectrum of research, both basic and applied; both for treatment and prevention. Under the able guidance of Dr. Claude Lenfant, that commitment continues.

Geisinger believes research is an essential component of medical advancement. Our staff members participate in clinical and basic research programs investigating cardiovascular, renal, malignant, and gastrointestinal diseases. In the cardiovascular area, Geisinger's researchers have pioneered studies involving a new hormonal receptor system in the heart.

Moreover, groundbreaking ceremonies in Danville, Pennsylvania -- adjacent to the Geisinger Medical Center marked the first step in a $57.5 million research initiative that will bring together senior investigators studying cellular and molecular biology. The early work of researchers in this area -- focusing on cardiovascular disease -- could lead to the development of drugs to treat coronary artery disease or to prevent the onset of hypertension.

It is well known that cardiovascular disease is prevalent among Americans, young and old. Cardiovascular diseases afflict more than 60 million people and cause almost one million deaths each year. Some 58 million persons suffer from hypertension, 6 million from coronary heart disease, and 2 million from cerebrovascular disease. Cardiovascular diseases are responsible for a loss of about one hundred billion dollars each year in productivity, wages and medical costs. Given this human suffering and economic consequence, it is imperative that NHLBI resources be expanded so that the current initiative in cardiovascular research can be maintained.

Geisinger's recommendations are aimed at maintaining this initiative. The desirability of exercising fiscal austerity should not supercede NHLBI's resources to continue its efforts in combatting the full panoply of cardiovascular diseases: hypertension, cerebral vascular disease, coronary heart disease, arrhythmias, heart failure and shock, congenital and rheumatic heart diseases, cardiomypathies and heart and circulatory system-infection.

To carry out its program, the Institute uses different mechanisms to accomplish specific objectives, including investigator-initiated research project grants -- the mechanism used to support most of the basic and clinical research that makes up the knowledge acquisition portion of the research continuum. Another important complement to research supported by investigator-initiated project grants is the Research Centers Program.

The Institute's Specialized Centers of Research (SCOR) programs in heart, lung, and blood diseases provide a unique environment for concentrating resources, facilities, and multidisciplinary expertise to conduct basic and clinical research. These center programs are designed to produce rapid clinical applications of basic science advances. They continue to be successful.

An example is the Institute's Hypertension SCOR Program. Hypertension remains a major risk factor for coronary artery and cerebrovascular disease. Through its hypertension SCOR's and investigator-initiated research project grants, the Institute is pursuing promising research leads on the basic mechanisms that regulate blood pressure, including the role of neurobiological factors, and elements in the diet such as sodium, calcium, potassium, and amino acids. This research may increase the chances of controlling hypertension through diet and other nonpharmacologic measures.

Although the NHLBI has made considerable progress in the cardiovascular area, the battle against these diseases is far from over. New information should be used to learn new insights about cardiovascular diseases. Indeed, the Institute is pursuing several promising areas of basic research.

The recent revolution in recombinant DNA technology has opened doors for research that were inconceivable a few years ago. Investigations of genetics with the use of sophisticated DNA and monoclonal antibody techniques have had a significant impact on heart, lung, and blood research. Research to develop new pharmacological interventions continues to produce new knowledge.

Geisinger enthusiastically supports this ongoing research, and we applaud NHLBI supported research that has contributed to such achievements as open heart surgery, cardiovascular and respiratory intensive-care units, diagnostic instruments for use in lung disease, and elimination of hepatitis B as a transfusion hazard.

Furthermore, we at Geisinger encourage the Institute to continue its prevention, education, and control efforts, particularly those programs that seek to reduce the prevalence of such risk factors as smoking, hypertension and elevated cholesteral levels. The Institute's emphasis on prevention and continued support for basic research through individual project grants and research centers that makes prevention possible will continue to have a positive impact on death and disability that results from diseases of the heart, lung, and blood.

Given the demonstrated economic soundness of biomedical research activities, increased appropriation levels for NIH, and particularly NHLBI, should be a national priority. Geisinger believes that in order for NHLBI to be able to continue to fulfill its mandate and provide the leadership which is crucial to our national biomedical research effort, an appropriation of 950.3 million is necessary for fiscal year 1987.

In closing, I would like to quote Dr. Harold L. Foss, Surgeon-in-Chief of Geisinger Medical Center from its beginning in 1915 to 1958. Dr. Foss once said, "Medicine is never static; its leaders can never enjoy the luxury of inertia." These words are as true today as they were back in 1915. Medical research cannot stand still. The Federal Government must not turn its back on biomedical advances of the future which could yield billions of dollars in health care savings.

On behalf of my colleagues at Geisinger, I thank you again for allowing us this opportunity to present our views.

Statement of Theodore J. Gothhelf, Chairman of the Board, Terri Gotthelf Lupus Research Institute

I am here today representing the Terri Gotthelf Lupus Research Institute, a national organization devoted to supporting and conducting research which will lead to finding the cause and cure for lupus. My other positions and interests may make my statement a little different from those of other organizations. Professionally, I am General Manager of OTC/Proprietary Drugs for Boehringer Ingelheim, the eighth largest drug company in the world. I am also the father of a daughter who was a victim of lupus. That is why I established the Institute. In my professional career, I have seen many drugs developed which led to the cure, prevention, or symptomatic relief of disease. The goal of the Institute is to do the same for lupus by:

- stimulating public and private lupus research;
- acting as a focal point for the principal lupus researchers in this country;
- disseminating information on their projects and results to others; and
- insuring that young scientists are encouraged to choose the field of lupus research as a lifetime career.

Several Institutes within the National Institutes of Health support research which will lead to finding the contributing factors causing lupus and how to prevent and cure the disease. The exact amount of research grant dollars is difficult to provide because so much of the investigative work is related to other diseases. There is no single source of information on lupus in the federal government.

Rapid strides are now being made in understanding the diverse defects of the immune system. We must not reduce the current level of support and lose the momentum which has been started. I also recognize that we must use our resources wisely. My testimony will reflect these dual concerns by:

- highlighting some of the progress which has been made in lowering the mortality rate associated with the disease;
- emphasizing the importance of federal support for research because of the relationship of lupus to other immune deficient diseases;
- suggesting how the effectiveness of the federal investment in lupus research can be improved; and
- proposing some initiatives for achieving greater cooperation between the public and private sector.

MISSION OF THE INSTITUTE

Before beginning these points, let me describe the mission of the Institute and why it was founded. Until the Institute was established, there was no single center focusing entirely on lupus research. The Institute is dedicated to supporting, coordinating and conducting clinical and experimental research in the field of lupus and related diseases. It is a new organization but we have been able to enlist the support of the outstanding scientists in lupus and immunologic research in the country. Through our advisors we are developing a strategy for influencing to a greater degree the direction of research in the etiology, diagnosis, and treatment of lupus.

The Institute was established because there was no other single focus for lupus research and, therefore, there was little coordination of the ongoing efforts. It serves as the center for carrying out a series of activities to document and share the results of current research efforts on lupus and related diseases; assemble an inventory of research findings; and publish information on the disease which can be used by clinicians and scientists, as well as by the public.

PROGRESS ACHIEVED

Systemic lupus erythematosus (SLE) is a spontaneously occurring, multisystem, inflammatory connective tissue disease of unknown etiology. According to available data, there are more than 50,000 new cases diagnosed each year, and the disease affects more than 500,000 people in the United States. That number is grossly understated. Unfortunately, there has been no national incidence or prevelance study so that we know more scientifically the number affected, their characteristics, and most common symptoms.

SLE usually begins in adolescence. Approximately 90 percent of patients are females. The most common clinical manifestations of SLE in decreasing order of frequency are: joint pain and swelling, fever, rash, nephritis, pleurisy, central nervous system involvement, pneumonia, and heart disease. Although SLE effects multiple body systems, the lesions or conditions that generally determine the course of disease are found in the kidneys.

Approximately 40 percent of lupus patients have renal involvement, the major cause of end stage renal failure. The overall ten-year survival rate has improved considerable for all lupus patients. In 1955, the average survisorship was 50 percent four years after diagnosis. Now over 95 percent of SLE patients survive five years and over 80 percent survive 15 years. However, those with nephritis have a five year survival of 67 percent. Those who do survive often have disabling complications, an important consideration because most of those affected are young women in their child-bearing years.

There are some interesting observations that can be made about SLE.

- It is one of the oldest diseases known. It is now clear that it is much more common than thought 20 years ago and is recognized as one of the most frequent serious disorders of young women.
- It frequently is misdiagnosed because of its multiple effects on the body and the similarity of the clinical manifestations to those of other diseases; for example, it has often been diagnosed as arthritis and treated as arthritis, incorrectly so. Arthritis is an inflammation of the joints and a less life threatening disease. It does not affect the vital organs, leading to death.
- Clinically, SLE is regarded as the prototypic immune complex disease in man, one of the new exciting areas of research carried out by the National Institutes of Health and in the private sector.
- Yet we still do not know the cause of lupus, nor how to prevent or cure the disease.

Let me add a final, timely observation. Dr. Tony Fauci, the Director of the National Institute of Allergy and Infectious

Diseases, is a lupus scholar as well as one of the leading experts on AIDS. Some of his remarks before the Appropriation Subcommittee just a year ago suggest the importance of lupus research. He stated that: "The study of lupus has probably shed more light on the complexities of immune function and given us more insight into a vast array of diseases than any other single disease directly or indirectly involving the immune system." He went on to say that of importance at this time is the fact that much of what has been derived from studies involving patients with lupus has been used to isolate the profound defect in immunologic function seen in patients with AIDS. Therefore, according to Dr. Fauci, the implications of studies of lupus are far reaching for diseases affecting the immune system and particularly AIDS.

FEDERAL RESEARCH EFFORTS

Research on SLE is supported by several Institutes at NIH. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) and the National Institute of Allergy and Infectious Diseases (NIAID) are both leaders in terms of the amount of grant support for lupus research performed in medical centers all over the country and in carrying out intramural research on SLE at the NIH Clinical Center.

The most recent report submitted by NIH (dated September 1983) to the House Committee on Appropriations on Lupus Erythematosus Research noted that: "There are few areas of connective tissue disease research that have engendered more interest during the past decade than the study of SLE. In addition to studies in man, excellent experimental models of SLE have been developed in certain inbred strains of New Zealand and American mice...Research in SLE has been very active and, as a result, new concepts of the nature of lupus have been formulated and subjected to critical testing."

Current research funding supports basic research to identify underlying causes of the disease. The clinical research supported by NIH has resulted in a number of new findings related to improved predictors of the outcome of lupus nephritis and the use of cytotoxic drugs to slow the progression of kidney failure. Some of the important research supported by NIH is in the manipulation of the immune system which will have broad implications for other immune disorders. Since the 1983 report, no cumulative analysis of the research results has been completed nor has there been a strategy developed to manage and coordinate the overall research efforts throughout NIH.

IMPROVING THE FEDERAL INVESTMENT IN LUPUS RESEARCH

I come here today as someone who believes that the cause of lupus can be found with a dedicated, managed research effort. I have a personal interest in making sure that this happens. But I am also a businessman who understands that resources are not unlimited. Therefore, I want to propose a few steps that will improve the effectiveness of the research program. None will cost more money. The results, I believe, will save money and lives in the longer term because we will get to the goal sooner.

These steps are based on the activities of the Institute over the past year in analyzing the federal role in lupus research. We have done our homework by learning as much as we can about federal support of lupus research. Let me share with you some of our findings and what I propose as solutions or positive steps forward.

First, we really don't know what is being spent on lupus research and the results of the government expenditures. In its report on the fiscal year 1983 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> "The Committee is concerned about lupus erythematosus, a chronic inflammatory disease of the connective tissue, ninety percent of whose victims are women--most often black

women in their childbearing years. The Committee would like to be kept informed of any positive research findings on the cause and treatment of lupus that may emerge from research relating to this disease sponsored or conducted by the various Institutes."

The only report issued was in September 1983. No report has been issued since that time.

Second, there is no national strategy or research agenda for lupus which would insure that the various efforts are directed and coordinated. The 1985 NIH authorization bill included a provision that a Lupus Erythematosus Coordinating Committee be established to plan, develop, coordinate, and implement comprehensive federal initiatives in research on the disease. The Committee, composed of the directors of seven institutes within NIH, is to meet at least four times a year until a report is submitted 18 months after enactment of the legislation. As far as I can determine, there has been little progress in meeting the purposes for which the Committee was established.

Third, there is little dissemination of information on ongoing research efforts supported by NIH. There also are few data disseminated on the results of the research which is supported with NIH funding. A substantial period of time elapses from the date that a research grant is submitted, through the review and award stage, the period when the research is conducted and terminating in the submission of final reports and data. The result may be duplication of research efforts because a scientist in one laboratory may not be aware that someone else is engaged in the same research.

My fourth observation in regard to the federal role in lupus research is the lack of active and ongoing cooperation between the public and private sector. There are obstacles, of course. There is a professional reluctance to share findings. We in the private sector often put too much emphasis on our responsibility to our stockholders. This is changing. The private sector has increased their financial investment in research, a positive step in this era of strained public resources. In 1984, pharmaceutical companies spent over $4 billion on research and product development.

IMPROVING THE RETURN ON THE RESEARCH INVESTMENT DOLLARS

In opening this statement, I said that I would suggest how the effectiveness of the federal investment in research could be improved. By maintaining the same level of federal support, we can increase the return on investment by making the research efforts less duplicative and more effective.

First, by developing a research strategy or agenda which would serve as a framework for lupus-related efforts. The agenda would be based on an assessment of the areas which offer the greatest potential for significant results, a determination whether there is ongoing research in that area, and an assignment of the relative priority of the area within the total agenda. In other words, there would be a plan developed by an eminent group of scientists to insure that the resources are used as effectively as possible.

Second, by establishing a process for disseminating information on current and completed research to the broader scientific community. In this way, an idea originating in one university laboratory would be shared with those working in private industry laboratories or at the NIH Clinical Center. Lupus research is too dynamic an area to be dependent on scientists learning results years after they are achieved.

Third, the public and private sectors must develop mechanisms for working more closely together. Research is expensive. The diverse actors in the two sectors should develop clear relationships, sharing knowledge and identifying areas of needed research.

My remarks are not meant to be entirely critical of the federal management of lupus research. Much has been accomplished in combatting this pervasive disease and we must not diminish the level of federal support. However, we need to make sure that the federal dollars are spent as effectively as possible. We in the Institute and in the private sector are willing to work with the federal government in developing a partnership to accomplish this goal.

STATEMENT OF THE LUPUS FOUNDATION OF AMERICA, INC.

Introduction

The Lupus Foundation of America (LFA), a voluntary health organization representing those Americans suffering from Systemic Lupus Erythematosus, welcomes the opportunity to submit a statement on FY 1987 appropriations for the National Institutes of Health. The LFA applauds the outstanding support and strong commitment exerted by Congress over the past several years for research into the causes, prevention, treatment and cure of immune system disorders, including Lupus Erythematosus. It is because of the continued efforts of Congress that NIH research initiatives have borne significant results, bringing us closer to learning about the immune system and the mysterious disease called lupus.

The Board of Directors, officers, and members of the LFA and its 95 affiliate chapters throughout the country recognize the difficulty Congress faces in attempting to balance national priorities and needs at a time of high budget deficits and a legislative mandate to balance the federal budget. But there can be no higher priority to this society than to protect and enhance the health of its citizens. We urge expanded funding for the programs of the National Institutes of Health which support biomedical research on immune system disorders and thus impact on the lives of millions of Americans.

The Special Case of Lupus Erythematosus

Lupus Erythematosus, commonly called lupus or SLE, is a disease of unknown cause, although its existence has been known for well over a century. Lupus strikes an individual's immune system, a complicated network of organs, tissues, cells, and circulating factors in the blood. Normally, the immune system protects individuals from infection by producing antibodies (protein molecules) that can react with foreign substances and lead to their elimination. In autoimmune diseases such as lupus, the body makes large quantities of antibodies that react against the person's own normal tissue. The immune system is overactive in lupus, while in other immune disorders, such as AIDS, this system ceases to function.

There are two main forms of lupus: Discoid Lupus Erythematosus, which involves only the skin and is a relatively mild disease, and Systemic Lupus Erythematosus, which can affect not only the skin, but also the liver, joints, kidneys, heart, lungs, central nervous system, or any other organ. The range of severity runs from mild aches and pains to a very serious disease that can be fatal to those afflicted. It may appear in different forms and with varying degrees of intensity in the same person.

Between 500,000 and 1,000,000 people in the United States are afflicted with systemic lupus, the more severe form, making it more prevalent than leukemia, muscular dystrophy, cerebral palsy, multiple sclerosis, and cystic fibrosis. Recent data suggest that the overall incidence of lupus in the United States is no less than one person in 2,000. More than 16,000 Americans develop lupus each year. Lupus is a prototype of other autoimmune diseases such as thyroiditis, rheumatoid arthritis, Sjogren's syndrome, and certain kinds of anemia. Continued and expanded lupus research can provide important answers to these other disorders of the immune system.

LUPUS DISCRIMINATES! The disease attacks females at an almost nine to one ratio over males. About 1 in 700 women between the ages of 15 and 64 is afflicted. Minority women are disproportionately affected; lupus strikes one adult White woman in 680; one adult Hispanic woman in 410, and one adult Black woman in 245. The onset of lupus most commonly occurs in the childbearing years.

More and more people are being diagnosed as having lupus. It is as yet unclear as to whether the incidence of this disease is rising or if new and more reliable diagnostic procedures account for the numerical increase.

Symptoms and Treatment. Lupus has been called "The Great Impersonator" because of the frequency in which initial episodes are diagnosed as other diseases. In fact, it is not unusual for a diagnosis of lupus to take five years, and in some situations as many as fifteen years! In the meantime, the individual may suffer any number or combination of a variety of symptoms: fatigue; diminished appetite and weight loss; frequent infections; chronic or recurrent low grade fever; abnormal hair loss; pain in the joints or joint swelling; blanching of fingers after exposure to the cold; red skin rash; photosensitivity; and easy bruising.

As long as the cause of lupus remains an enigma, there is no specific and complete treatment. Although a cure is not now possible, control of the disease is. With early recognition and improved treatment, patients with lupus can live longer and less debilitating lives. The current mainstay of treatment is medication. The majority of drugs used to treat lupus suppress the disease process itself, decrease inflammation, alter immune system function, and/or help to maintain function in other body systems. Steroids, the most well known of which is cortisone, are often used to treat lupus patients. A disadvantage is that this is a powerful drug that can cause harmful side effects. Worse than steroids are cell poisons that may have to be used if the patient is unresponsive to other drugs.

How Far Have We Come? Almost all that we know about lupus has been learned in the last 15 years. The importance of the T and B cells in the immune system and the knowledge that these cells function by secreting certain factors was recognized only within the last decade and a half. Medical scientists are now beginning to examine the interactions of the immune system, the endocrine system, and the nervous system. These current investigations may help shed light on the role of the patient's attitude in a number of diseases. New therapeutic approaches are also being introduced or intensively investigated. These include kidney transplants, pulse therapy, combination therapy, plasmapheresis, intravenous cyclophosphamide, use of monoclonal antibodies, immunoreplacement therapy, and development of new hormonal means of therapy. There is no doubt that the rapidly developing knowledge of the immune system and its regulatory mechanisms is leading to an increased understanding of lupus. With continued and expanded research efforts, there is great promise of dramatic and improved changes in the treatment of this disease and related immune system disorders.

Living with Lupus. Where would we be without past, current and anticipated biomedical research? In the words of one lupus patient:

> With lupus...a patient struggles against pain, dizziness, nausea, and fatigue to maintain a relationship with the world on even a minimal level. At work, one lives with the constant fear of possibly losing employment because of poor performance. There is worry about children, husband or wife, death and dying. There is the need to understand the illness, to know why one feels that way, and to find ways to deal with one's plight.

Lupus can result in pain, disability, and sometimes mortality. The cost to the individuals suffering from this disease can be measured in the quality of their lives, their ability to contribute to society, to develop and sustain professional careers, family relationships, and a sense of psychological and physical well-being. Sometimes, life itself is at stake.

There are costs to society, as well. The American economy is effected by lupus and other immune system disorders; public funds are diverted to increased medical care costs, lost wages and productivity, lost taxes, increased social service costs, and increased disability payments. If a cost analysis is applied, it is certainly more economical for this society to use its resources to control and cure disease than to sustain, for an indefinite period, the vast number of dollars spent as a consequence of disease. Placing biomedical research at the forefront of this society's priorities is not only a practical investment in the human resources of the United States, but a humane and responsible decision.

Research advances within the past decade have brought about improved treatment, disease control, and better diagnostic methods; accelerated and targeted research efforts now and in the future will likely ameliorate, prevent and cure diseases. The cuts proposed in the programs of the National Institutes of Health threaten not only to curtail progress, but to bring to a halt the important work now underway. Losing momentum in biomedical research through reduced or even constant funding levels means a serious loss of research opportunity for many years to come, particularly when one considers that new and potential researchers will be dissuaded from entering biomedical work. The consequences of proposed budget cuts will be counted in human lives.

The Public Role

The intramural and extramural research programs and support of the National Institutes of Health account for the major progress achieved in discovering new diagnosis and treatment knowledge about lupus. Two NIH institutes - the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Arthritis, Diabetes, Digestive and Kidney Disorders (NIADDK) have supported significant lupus research. The initiation in 1985 of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has brought the hope of even greater emphasis on, and support for, lupus research.

NIADD research on lupus includes studies on the basic biology and chemistry of the immune system and its function in health and diseases. Intramural and extramural scientists are studying underlying immune mechanisms and their regulation; hypersensitivity and inflammation associated with immune reactions; and other suspected causes of lupus, including infectious agents, drug sensitivity, and genetic predisposition. The many physiological systems and body organs involved in lupus have led to significant research avenues by NIADDK, particularly on lupus as a connective tissue disease. NIADDK is also studying the effects of lupus on the kidney, blood vessels, joints and skin.

It is only with the ongoing information resulting from these research studies that new and more effective methods of therapy, prevention and cure can occur. While the Lupus Foundation of America sponsors small grant awards and fellowship programs each year for researchers investigating Lupus Erythematosus, no voluntary or private organization has the mandate, funding capability, or personnel to address the magnitude of the task.

Recommendations

The LFA supports the recommendations of the National Coalition on Immune System Disorders, the Ad Hoc Group for Medical Research, and the Coalition of Organizations Concerned with the Programs of the NIAMSD for a $6.1 billion budget for the NIH. This sum represents a modest increase of about 1.4 percent over the current services budget and allows the basic and clinical research activities initiated under the FY 1986 congressional appropriations to continue, thus insuring the translation of that research and technology into medical practice to the benefit of those afflicted with lupus and other immune system disorders. The continued training of qualified biomedical investigators is also made possible.

The LFA further recommends that:

- The provisions of P.L. 99-158, the Health Research Extension Act of 1985 establishing the National Institute of Arthritis and Muscoloskeletal and Skin Diseases (NIAMS) be implemented at the level of $151,650,000 (as proposed by the Coalition of Organizations Concerned with the Programs of NIAMSD) to maintain research efforts at current services levels and allow for the initiation of new, as well as continuation grants.
- The recommendations of the time-limited Coordinating Committee on Lupus Erythematosus created under P.L. 99-158 to plan, develop, and implement comprehensive Federal initiatives in lupus research be implemented in full, thus creating new and broadened avenues of lupus clinical investigations.
- DHHS, particularly NIH and the Public Health Service, expand efforts to educate the public and health professional community about the nature and consequence of immune system disorders to assist in early diagnosis and treatment.

The Lupus Foundation of America

Until biomedical research solves the mysteries associated with the awesome disease of Lupus Erythematosus, the LFA and its 95 affiliate chapters will continue to assist persons with lupus and their families to ease the emotional, physical, and practical burdens associated with its course and outcome.

The LFA, founded in 1977, seeks to: provide greater public and professional awareness of this disease and its consequences; intensify publicly sponsored research programs and support and initiate new research efforts through a program of grant awards and fellowships; strengthen physician training to aid in prompt diagnosis and improved therapy; and provide information to patients, their families, government, and the concerned public to encourage understanding, support, and medical advances.

The LFA affiliate chapters, located in almost every state and major U.S. city, are frequently staffed by volunteers. Often, local medical advisory boards of concerned and knowledgeable health professionals assist in the work of the chapters. The chapters put on educational programs for patients and the community and produce and distribute literature on the disease. By taking part in chapter activities, patients with lupus have the chance to learn about their illness and how to live with it, and to develop a feeling of satisfaction from helping others with the same problem.

Please help us help. A cure is possible, but public support is essential.

STATEMENT OF J. ALFRED RIDER, M.D., PH.D., PRESIDENT, CHILDREN'S BRAIN DISEASES FOUNDATION, SAN FRANCISCO

Senator WEICKER. Our next witness is Dr. Alfred Rider, president of the Children's Brain Diseases Foundation, San Francisco.

Dr. RIDER. Senator Weicker, it is always a pleasure to come before you. I think you have one of the best chairmen of any of the committees I have seen. You really have the interest of research and people at heart.

Before I start, I would like to make a little homily. The roof is leaking, and we have a chance of fixing the roof, or we can repair the damage to the furniture and the inside of the house, and so forth. I think that the most inefficient thing that we can do is to decrease the research budgets, and stop the kind of research that is going to stop the roof from leaking. With that, I will get into my own specific statement.

As you know, I am Dr. Rider, the president of the board of trustees of the Children's Brain Disease Foundation. I speak specifically to support the budget request of the National Institute of Neurological and Communicable Disorders and Stroke.

I speak today specifically with reference to research funding for Batten's disease. This is a neurological disorder which has an incidence as high as one in 12,500 births. Similar to other genetic disorders, it is probably the most common neurogenetic storage disease in children.

It usually manifests itself in previously normal children at the approximate age of 4 to 8, and it is characterized by slow progression to clumsiness, stumbling, failure of vision, seizures, changes in personality, and dropping of scholastic grades.

The disease eventually leaves the children totally disabled, unable to care for themselves, and usually ends in death in the late teens or twenties, or early in the thirties. The cost of taking care of one of these children through their lifetime may run well over $1 million, and this has to come from somebody's budget somewhere.

The changes which occur in the brain in these children are quite similar to many of the changes in the aging person, thus effective treatment for Batten's disease may also allow us to alter the aging process of senility in all humans.

The basic cause of the disease is probably due to a defect in the peroxidase enzyme in the brain. Research must be directed toward obtaining further evidence of this and initiate treatment with agents designed to block the accumulation of peroxidase or enhance its degradation.

We have always supported the budget presented by the National Institute of Neurological and Communicative Disorders and Stroke. We are pleased that the committee recommended an appropriation of $428 million for fiscal year 1986, which represented an increase of $32 million over fiscal year 1985.

However, in spite of the wording in the 1986 House appropriation bill, namely, "The committee reiterates its concern about research on Batten's disease, and requests that the Institute actively solicit applications of quality for research on Batten's disease" very little money has been spent by the National Institute of Neurological and Communicative Disorders and Stroke for 1985–86. In fact, in 1986–87, we are aware of only one modest grant being funded.

In fairness, however, they are attempting to develop several research centers on neurogenetic diseases, and I think that will be of help.

We feel that this gross discrepancy must be remedied and urge the committee to use the following language in its appropriation bill. I know that you don't like this, but I am going to present it anyway.

> The committee is concerned upon learning that in spite of last year's recommendation requesting research on Batten's disease that little research was funded in 1986. Therefore, it requests that the National Institute on Neurological and Communicable Diseases and Stroke actively solicit applications for grants of quality for Batten's disease and to fund up to $1 million for research of Batten's disease.

If this is done, I am confident that in the very near future, we will have a cure of this disease, and millions of dollars are going down the drain now for supportive care that could go for other purposes.

Thank you very much.

PREPARED STATEMENT

Senator WEICKER. Thank you very much, Dr. Rider.

I don't think that we need the language in the bill. I think that this is a matter that can be raised directly between the subcommittee and the National Institutes of Health.

I am sorry that that has occurred because I know how diligent you have been in pursuing this matter, appearing before this committee. If indeed we did give a directive, which was not followed, I would like to know further about it. So we will do the best we can on this.

Dr. RIDER. Thank you.

[The statement follows:]

STATEMENT OF J. ALFRED RIDER

Summary of Recommendations

Batten's disease is a neurological disorder which may have an incidence as high as 1 in 12,500 births, similar to other genetic disorders. It is probably the most common type of neurogenetic storage disease in children. It usually manifests itself in previously normal children at the approximate age of 4 to 8 and is characterized by a slow progression of clumsiness, stumbling and failure of vision, seizures, changes in personality and dropping of scholastic grades. The disease eventually leaves them totally disabled and unable to care for themselves and usually ends in death in the late teens or twenties and rarely, into the thirties. The cost of taking care of these children through their lifetime may run well over one million dollars. The changes which occur in the brain in these children are quite similar to many of the changes in the aging person. Thus, effective treatment for Batten's disease may also allow us to alter the aging process of senility in all humans.

The basic cause of the disease is probably due to a defect in the peroxidase enzyme system in the brain. Research must be directed toward obtaining further evidence of this and initiate treatment with agents designed to block the accumulation of peroxidase or enhance its degradation.

We have always supported the budget presented by the National Institute of Neurological and Communicative Disorders and Stroke. We were very pleased that the Committee recommended an appropriation of $428,517,000 for fiscal year 1986 which represents an increase of $32,858,000 over fiscal year 1985.

However, in spite of wording in the 1986 House Appropriation Bill namely: "The Committee reiterates its concern about research on Batten's disease, and requests that the Institute actively solicit applications of quality for research on Batten's disease" very little money has been spent by the National Institute of Neurological and Communicative Disorders and Stroke. We are aware of only one modest grant being funded for fiscal year 1986-1987.

We feel that this gross discrepancy must be remedied and urge the Committee to use the following language in its Appropriation Bill:

> "The Committee is concerned upon learning that in spite of last year's recommendation requesting research on Batten's disease that little research was funded in 1986. Therefore, it requests that the National Institute of Neurological and Communiicative Disorders and Stroke actively solicit applications for grants of quality for Batten's disease and to fund up to $1,000,000 for research on Batten's Disease."

Statement

I am Doctor J. Alfred Rider, President of the Board of Trustees of the Children's Brain Diseases Foundation. It is a pleasure to testify before the Senate Appropriations Sub-Committee on Labor, Health and Human Services, Education and Related Agencies and support the budget requests of the National Institute of Neurological and Communicative Disorders and Stroke.

I speak today specifically with reference to research funding for Batten's disease. This is a neurological disorder which has an incidence as high as 1 in 12,500 births, similar to other genetic disorders. It is probably the most common neurogenetic storage disease in children.

It manifests itself in previously normal children at the approximate age of 4 to 8 and is characterized by a slow progression of clumsiness, stumbling, failure of vision, seizures, changes in personality and dropping of scholastic grades. The disease eventually leaves them totally disabled and unable to care for themselves and usually ends in death in the late teens or early twenties and rarely in the thirties.

One of the most promising theories about the disease has resulted from the discovery of an abnormality in the peroxidase enzyme system in the brains of children with Batten's disease. This results in an accumulation of a yellow pigment, ceroid lipofuscin, in the brain cells producing slow destruction and progressive deterioration. These changes are quite similar to the changes that take place in all brains as they age. Thus, effective treatment for Batten's disease might delay the normal aging process.

In the last year, research has been directed toward improving and expanding upon a blood chemistry test. These studies seem to indicate that there are four sub types of Batten's diseases each having a specific peroxidase enzyme abnormality.

Additional studies have been done on the Kopang dogs and in sheep which have a disease similar to Batten's disease in humans.

In order to further world wide recognition of this disease, I presented a paper entitled Batten's disease at the age pigments conference in Italy in June 1985. The proceedings of the conference will soon be published by NVU Science Press (Amsterdam).

Research is the only way to solve this disease and prevent the devastating tragedy in families who have children so afflicted and effect tremendous savings to society as a whole. The cost of care for each child is enormous and may be as high as $100,000 or more per year. Thus, 10 children such as these would cost more per year than the funds we are requesting.

Once the exact nature of this defect is established then full effort will be devoted to prevention and treatment. In addition to genetic counseling, therapy will be directed towards enzyme replacement and/or treatment with anti-oxidants.

The Children's Brain Diseases Foundation is doing the best it can to stimulate research on Batten's disease. For example, we are in the process of assisting with the development of two Batten disease centers, one at the University of Indiana and one at the Institute for Basic Research in Developmental Disabilities in New York.

Unfortunately, our abilities to raise money from private sources are limited, and the major monies must come from the NIH. There are over thirty five principal investigators from major universities, medical centers and institutes throughout the world interested in various phases of research pertaining to Batten's disease. (See addendum.) These researchers are in dire need of monies to continue their work.

We have always supported the budget presented by the National Institute of Neurological and Communicative Disorders and Stroke. We were very pleased that the Committee recommended an appropriaton of $428,517,000 for fiscal year 1986 which represents an increase of $32,858,000 over fiscal year 1985.

However, in spite of wording in the 1986 House Appropriation Bill namely: "The Committee reiterates its concern about research on Batten's disease, and requests that the Institute actively solicit applications of quality for research on Batten's disease" very little money has been spent by the National Institute of Neurological and Communicative Disorders and Stroke on Batten's disease.

I have personal knowledge of only one grant being approved for research on Batten's disease at a very modest level. The title of the grant is "Lipofuscinogenesis in the Retinal Pigment Epithelium".

However, in fairness, I do know that the National Institute of Health is trying to assist in the development of one or more neurogenetic research centers around the country. Whether Batten's disease would play a prominent role in research in these centers is still unknown.

We feel that this gross discrepancy must be remedied and urge the Committee to adopt the language as outlined above and further request that you add to this the recommendation that research on Batten's disease be funded up to $1,000,000 a year.

If funding is provided, the chances of the development of a specific treatment program in the near forseeable future appear to be very good.

Addendum

Scientists Actively Working in Research on Batten's disease

1. Doctor Donald Armstrong
   Formerly at the University of Florida, Department of Opthalmology
   Relationships of Peroxidase to Batten's disease
   Canine Retinal Degeneration: An Approach to Therapy
   Peroxidase Deficiency & Peroxidase Regulating Enzyme
   Peroxidase Activity in Human and Canine Ceroid-lipofuscinosis, with Special Emphasis on the Eye

2. Doctor Robert J. Baumann
   Department of Neurology
   University of Kentucky & Section on Epidemiology OBE, Office of the Director, NINCDS, Bethesda, Maryland
   Leukocyte Ultrastructure

3. Doctor Milton Brightman
   Lab. of Neuropathology & Neuroanatomical Sciences
   NINCS & National Institutes of Public Health/Department of Health and Human Services
   Transport of Horseradish Peroxidase Across Blood Brain Barrier

4. Doctor Glyn Dawson
   Associate Professor,Depts.of Pediatrics and Biochemistry
   The University of Chicago
   Pre-Natal Diagnosis and Enzyme Replacement Therapy
   Approaches to the Detection of Neuronal Ceroid Lipofuscinosis in Cultured Skin Fibroblasts

5. Doctor T. L. Dormandy
Whittington Hospital, London
Free Radicals and Lipopigments

6. Doctor Edward Dratz
Associate Professor of Chemistry & Biochemistry
University of California, Santa Cruz
Measurement of Fluorescent Lipopigment, Peroxidized Fatty Acids, Vitamin E, Effects of Antioxidants on Lipopigment Formation

7. Doctor Graig E. Eldred
Institute of Opthamology, University of Missouri-Columbia, Missouri
Lipofuscinogenesis in the Retinal Pigment Epithelium

8. Doctor Paul Glees
University of Cambridge, Anatomy School, Cambridge
Electron Microscopic Studies on Neural Lipofuscin: Accumulation and Removal
The Effects of Centrophenoxine in the Central Nervous System

9. Doctor H. H. Goebel
Division of Neuropathology, University of Gottingen
The Ultrastructural Spectrum and Diversity of Lipopigments in the Neuronal Ceroid-Lipofuscinosis

10. Doctor John M. C. Gutteridge
Division of Antibiotics, National Institute for Biological Standards and Control, Holly Hill, Hampstead, London
Flurorescent Products of Phospholipid Peroxidation: Formation and Inhibition in Model Systems

11. Doctor Egill Hansen
Department of Opthalmology, Rikshopitalet, The National Hospital, University of Oslo, Norway
The Significance of Psychophysical and Electrophysical Methods in the Diagnosis of Juvenile Neuronal Ceroid-Lipofuscinosis

12. Doctor Ann Harden
Department of Clinical Neurophysiology, The Hospital for Sick Children, London
Neurophysiological Studies in Children with so-called Neuronal Ceroid-Lipofuscinosis

13. Doctor Denham Harman
The University of Nebraska Medical Center
Brain Lipid Composition

14. Doctor K. U. Ingold
Associate Director, National Research Council of Canada
Division of Chemistry
Resistance to Oxidation and the Natural Antioxidant Levels in Membranes from Human Cells

15. Doctor Gunde Egeskov Jensen
The Laboratory of Biochemistry and Toxicology, The Institute of Biology and Chemistry, University of Roskilde, Denmark

Glutathione Peroxidase Activity in Leucocytes, Erythrocytes and Serum from Juvenile Form of Neuronal Ceroid-Lipofuscinosis

16. Doctor R. D. Jolly
Department of Veterinary Pathology and Public Health, Massey University, Palmerston North, New Zealand
Ceroid-Lipofuscinosis: The Ovine Model
Studies on Mannosidosis and Ceroid-Lipofuscinosis in Cattle, Sheep and Dogs

17. Doctor Edwin Kolodny
Associate Director, Eunice Kennedy Shriver Center For Mental Retardation, Inc., Waltham, Massachusetts
Pathogensis of the Neuronal Ceroid-Lipofuscinosis

18. Doctor Nils Koppang
Veterinaerinstuttet, Oslo, Norway
Histochemical Evidence of Lipid Peroxidation in Canine Ceroid-Lipofuscinosis

19. Doctor Martin M. Maltempo
Assistant Professor of Physics, University of Colorado Medical Center
Monitoring of Peroxidase and Free Radicals in Canine Retinal Tissue Subject to a Degenerative Disease in which there is an Accumulation of Pathologic Lipopigments of the Ceroid Type: A Model for Batten's disease

20. Doctor Jaime Miguel
NASA, Ames Research Center, Moffett Field, CA
Analysis of Pigment Lipofuscin

21. Doctor Erling Gronvold Olsen
University Eye Department, Rikshospitalet, University of Oslo, Norway
Fluorescein Angiography in Ceroid-Lipofuscinosis

22. Doctor Vimal Patel
Assistant Professor of Pathology
Indiana University School of Medicine
Antioxidant Treatment of Batten's disease

23. Doctor Alan K. Percy
Associate Dean, Office of Research, Charles R. Drew Postgraduate Medical School, Los Angeles
Salutory Effect of Selenium, Erythrocyte Glutathione Peroxidase

24. Doctor Michel Philippart
Neuropsychiatric Institute, University of California, Los Angeles
Treatment of Batten's disease with Antioxidants

25. Doctor Mark Poznansky
Associate Professor of Pathology, University of Alberta
Enzyme Replacement and Enzyme Engineering

26. Doctor Raju Pullarkat
New York State Institute for Basic Research in Mental Retardation, Staten Island, New York

Lipopigments in Aging and in Ceroid-lipofuscinosis
Docosahexaenoic Acid Levels in Brains of Various Forms of Ceroid-lipofuscinosis

27. Doctor Julius Schultz
Director, Pananicolaou Cancer Research Institute, Miami, Florida
Discovery and Characteristics of Leukocyte Peroxidase and the Purification and Administration to Animals

28. Doctor Gunther Schwendemann
Division of Neuropathology, University Hospital, Eppendorf, Hamburg
Diagnosis of Juvenile Ceroid-Lipofuscinosis by Electron Microscopy of Lymphocytes and of Rectal, Skin and Sural Nerve Biopsy Tissue

29. Doctor A. N. Siakotos
Professor of Pathology, Indiana University Medical Center
Development of a Reliable Blood Test for Batten's Disease
Recent Developments in the Isolation and Properties of Autofluorescent Lipopigments

30. Doctor P. E. Spoerri
Department of Histology and Neuroanatomy, University of Gottingen, Sweden
Ultrastructural Age Changes in Neurons and Myocardium in Culture. The Effects of Centrophenoxine on Age Pigment

31. Doctor Satish Srivastava
Department of Human Biological Chemistry & Genetics
The Unviersity of Texas Medical Branch
Purification and Properties of Leukocyte Peroxidase
Biochemical Studies in Neuronal Ceroid-Lipofuscinosis

32. Doctor Al Tappel
Division of Food Science & Technology, University of California, Davis
Properties and Functions of Glutathione Peroxidase and Pentane Analysis of Lipid Peroxidation Damage to Quantitate Effects in Nutrition

33. Doctor T. Westermarck
Rinnekoti Institution for the Mentally Retarded, Espoo,
Institute of Radiation Protection, Helskinki, Finland
Sodium Selenite Absorption and Losses in Spielmeyer-Sjogren Type of Neuronal Ceroid-Lipofuscinosis (Batten's disease) Using Total Body Counting for 75 SE Detection
Studies on the Effects of Selenium Administration to Neuronal Ceroid-Lipofuscinosis Patients with Special Reference to Reduced Gluthathione

34. Doctor John R. Wherrett
Professor of Neurology Program, University of Toronto
Isolation of Fluorescent Material in the Juvenile Form of Batten`s disease

35. Doctor Leon Wolfe
Hopital Neurologique de Montreal, Montreal Neurological Hospital, Canada
Characterization of the Accumulated Retinal Compounds in Batten's disease
An Analysis of Urine Sediment in Subjects with Batten's disease

STATEMENT OF SUSAN DEHAAN, PRESIDENT, NATIONAL ICHTHYOSIS FOUNDATION

ACCOMPANIED BY:
ROBERT MASSEY
SARAH MASSEY

Senator WEICKER. Our next witness is Susan DeHaan, president of the National Ichthyosis Foundation.

Ms. DEHAAN. With me today is Robert Massey from Fountainhead, SC, and his mother, Sarah.

Senator WEICKER. Robert, Sarah, nice to have you with us. I think you should also know that Senator Hollings wanted to be here, but he has to chair another hearing. I send you his good wishes also. It is a great pleasure.

Robert, you are a very brave person to be here. If you have to move around a little bit, because I understand that it is tough for you to sit, you just go ahead and move around a little bit.

Ms. DEHAAN. The National Ichthyosis Foundation appreciates the opportunity to be here as a member of the coalition of organizations concerned with the programs of the National Institute of Arthritis, Musculoskeletal and Skin Diseases.

The foundation is a new organization. It has actually been in existence for about 5 years now. We have approximately 7,500 members in the United States. I believe that as the foundation becomes more known to people with ichthyosis, we will find a greater number of Americans suffering from this disorder.

I became involved with the foundation when I was teaching behavioral science at UC Medical School, and we had a 7-year-old little girl who was a patient there, whose life had been completely devastated physically and psychologically by this disease.

Probably many of you are not familiar with this disease, so I will take some time to talk with you about what it is, and how it affects the lives of the people who live with it.

Ichthyosis is a genetic skin disorder. Scientists have identified 4 different types and about 20 varieties. That is the stage of knowledge as it is today. Robert has epidermalitic hyperkeritosis, which is a disorder of scaling and blistering. People born with this have very tight skin. The outer layer is either over producing skins, or not shedding properly, so that it is a very taught kind of existence for them, and their whole life is spent, really, trying to exfoliate the skin or to keep it soft.

Depending on the type, it affects, we think, 1 in every 100,000 people. We really don't have accurate statistics on it because we often find that people have lived their whole lives thinking that they were the only one with this disorder. As we become more known, we find out that there are a lot of people who are actually suffering from it. We estimate that about 5,000 people in the country actually have very severe cases of this.

What it means in the life of the person is that they have this very tight scaling kind of skin. Sometimes, the scales are very large and brown. I brought some pictures so you could see what I am talking about. These are the two types of lameli ichthyosis that have been identified. Actually, the research on this has come from the National Institutes of Health. This is a new advance in research, just finding these two different types of lameli ichthyosis where there are large brown scales, dead skin all over the body, or white scales. The person continually produces this. If you go into the home of somebody who has ichthyosis, there are scales all over the house, and it has an odor about it with the dead skin. Of course, if the person goes about in society, people have the view that they are either dirty, or something like this. The children go to school, and they hear many stories of them being scrubbed daily at school, and being accused of not being clean. There is that odor; they have that kind of problem.

In addition to the scaling as in Robert's case, he also has blistering, which makes it difficult for him to sit or to have clothing close to him. He has to be quite careful because with this comes the infection. When they overproduce the skin, and the dead scales, people with ichthyosis often have chronic staph infections or chronic fungal kinds of infections which prevents them from having surgery that they need to have. They have to constantly be on some type of antibiotic or antifungal kind of medication.

Accompanied with ichthyosis is often severe pain because of the bleeding and infections, or a constant itching. What I have seen in my work often is people who have ichthyosis are very compulsive about constantly picking at themselves and trying to keep clean. Their whole existence focuses on the skin, which can be very disfiguring for some people.

Children have loss of motion if their skin is very tight. We have a number of kids who are in wheelchairs, who are not able to attend school, or to go about in society. It is not uncommon to get letters from people with ichthyosis who have lived their whole life inside their homes, and just stopped going out because of the kind of social ostracism that they experienced.

Heat maintenance of the body is a chronic problem because the skin doesn't perspire properly, it doesn't breathe properly. So even in normal kind of weather, if a person with ichthyosis gets involved in doing activities at high temperatures, they will pass out, faint. So it is a continual problem.

When Sarah and Robert came, we had to make special arrangements for them, so that Robert doesn't become overheated.

PREPARED STATEMENT

Senator WEICKER. Thank you. We will place your statement in its entirety in the record at this point.

[The statement follows:]

STATEMENT OF SUSAN NYE DEHAAN

INTRODUCTION

The National Ichthyosis Foundation as a member of the coalition of organizations concerned with the programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, is pleased to have this opportunity to submit its statement regarding FY 1987 Appropriations for this new NIH research institute. We are especially concerned with funding for NIAMS in FY 1987 as this is the first opportunity for Congress to address the research needs of the programs encompassed by this new institute. The National Ichthyosis Foundation and those suffering from this often devastating skin disorder are urging appropriate levels of funding for the new institute to insure that its research program will be realized in full and effective fashion.

RESEARCH NEEDS

The ichthyoses are a group of genetic skin disorders which affect the stratum corneum, or outer layer of skin. Four major types of ichthyosis and twenty varieties have been identified. Depending on the type, the skin either grows too fast or is retained too long. In either case, it becomes thick, scaly and dry. It is estimated that over 1,000,000 Americans suffer from some form of ichthyosis, 5,000 of which have the more severe forms.

In the severe and rarer forms of ichthyosis, other diseases may also be present. These may include deafness, retardation, still births and others involving parts of the body vulnerable to this skin disease. People suffering from the ichthyoses experience a number of physical problems as a result of it. Because the skin is thick, it does not breathe and perspire properly and body temperature rises causing serious and critical conditions. Further, even body temperature also rises with exertion in a cool environment, and short exposure to the sun results in severe burning.

The inordinate thickness and scaling of the skin makes it an ideal environment for bacteria and fungal growth. Therefore, infection is a constant problem. It is not uncommon for those suffering from ichthyosis to have complete hair loss, chronic eye-ear infections, irritation, bleeding or blistering of the skin where clothing rubs or pressure is applied to a body part such as when one sits down.

Ichthyosis interferes with the normal physical and psychological development of those suffering from it. Since there is no effective treatment or cure for ichthyosis, care of the skin becomes a constant ritual. Those suffering from the less severe forms are bothered by the daily rituals of trying to exfoliate the skin and soften it. In the more severe forms, life becomes a drudge of daily skin care management. People sleep in plastic wraps and remain "greased" throughout the day. Skin scales are in abundance throughout the ichthyotic home - the dead skin leaving an unmistakeable odor about the person. Some exfoliating treatments contain acids which eat through clothing and furniture. For some, decreased motion due to hard and inflexible skin is a problem - they may be in wheelchairs. In young children, this inhibited motion interferes with the normal exuberance of childhood and has a chronic disabling affect on learning and maturation Because of these chronic motion, thermal and infection problems, adults suffering from ichthyosis are excluded from employment which requires movement or where sanitary conditions and heat is a problem and children do not participate in the normal activities of childhood.

In addition to the physical affects of ichthyosis and the day-to-day drudge of managing it are the social and psychological difficulties encountered because of a shocking physical appearance.

A person's disfigured appearance coincides with the type of ichthyosis they have. Some have red underlying skin with layers of white flakes on top. The taught skin around they eyes and loss of lashes gives them an unnatural appearance. Others have large blackish/brown scales entirely on their skin surface rendering their skin appearance similar to a reptile's. Still others have scales and blistering on reddened skin - all are severely disfigured.

People seeing someone with ichthyosis are often frightened or horrified, shunning the victim. It is not uncommon for ichthyosis sufferers to be stared at, questioned, maligned, teased, and excluded by others due to their disfigured appearance and the observer's unfounded fears of contagion or misunderstanding of the disease.

In our work with ichthyosis sufferers, we note similar psychological characteristics in those who suffer with it. There is a general sense of impairment, shyness, lack of confidence, lack of experience in the developmental tasks of their peer groups, lack of normal social experiences and reclusiveness. These feelings become particularly acute in children as they start school and are out of the protective support of their family for the first time. A pervasive sense of differentness and unworthiness becomes part of the personality resulting in individuals who remain chronically impaired and whose full potential never develops.

The physical, social and psychological problems associated with ichthyosis, particularly in its more severe forms, restricts individuals, keeping them out of the normal mainstream of life and certainly out of the competitive work force. Thus, they are often unable to care for themselves. Along with the other serious diseases which come under the purview of the new institute, the resulting disabilities of those whose suffer from them cost the American economy many billions of dollars each year in medical care, lost wages and productivity, lost taxes, increased disability, and increased social services.

In addition to our urging of appropriate funding levels for hard research, we are also interested in programs that would provide for the immediate supportive needs of these individuals and their families. For example, young parents with no previous history of family ichthyosis, are emotionally immobilized and overwhelmed at the birth of an ichthyotic child. They are isolated, believing they are the only people with the disorder. Some adult sufferers have never seen another person with the disease and assumed no one else had it. Further, there are diagnostic problems. This being a rare disease, many physicians have little experience with it and families often go from doctor to doctor at great emotional and financial expense before getting a correct diagnosis. Ichthyosis sufferers are often unclear about the genetic nature of their disease and society at large has no knowledge of it. Therefore, programs geared toward providing educational and family support services around ichthyosis and the other rare diseases under NIAMS would be of great and extreme help to those suffering from them.

CONCLUSION AND RECOMMENDATIONS

The National Ichthyosis Foundation supports the recommendations of the coalition of organizations concerned with the programs of the National Institute of Arthritis and Musculoskeletal. These recommendations are presented in the coalitions' statement paper of this date. We are aware there are many urgent national needs and limited financial resources. However, since ichthyosis is a genetic defect in the population at large, it will continue to be passed down through the generations until its cause is determined and eradicated. In our view, the extreme disability, disfigurement and impairment experienced by those who suffer from ichthyosis and the other diseases encompassed under NIAMS make funding research to improve the quality of their lives a high national priority. Research into ichthyosis and these other diseases will not only benefit the 50,000,000 Americans who suffer from them, but also the population at large. It is through enhanced knowledge of how these diseases work that we gain a greater understanding of normal life problems, in our case, healthy skin properties - the largest and most apparent organ of the body that most of us take for granted.

We urge Congressional enactment and Presidential approval of appropriations for NIAMS FY 1987 at the level the coalition recommends, as the minimum necessary to firmly establish NIAMS and to begin the research effort essential to finding the answers to the diseases addressed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Your consideration of this issue is greatly appreciated by the National Ichthyosis Foundation and those who suffer from this rare and devastating disease.

Attachments

TO WHOM IT MAY CONCERN REGARDING : ROBERT ANTHONY MASSEY

ROBERT WAS BORN WITH EPIDERMOLYTIC HYPERKERATOSIS (A FORM OF ICHTHYOSIS). THIS CONDITION, THOUGH VERY RARE, IS NOT CONTAGIOUS. UNTIL ROBERT WAS 8 1/2 YEARS OLD, WE KNEW OF NO ONE ELSE WITH THIS CONDITION. WE NOW KNOW OF A FEW OTHERS, BUT NONE LIVE NEARBY.

ROBERT HAS BEEN EXAMINED BY DOCTORS AT DUKE, CHAPEL HILL, AND EMORY, AS WELL AS DOCTORS IN NORTH AND SOUTH CAROLINA. WE ARE IN CONTACT WITH DOCTORS AT THE SAN FRANCISCO MEDICAL CENTER AND THE NATIONAL INSTITUTE OF HEALTH. AT THIS TIME, THERE IS NO KNOWN CURE; THE MOST WE CAN DO IS TO KEEP HIM COMFORTABLE.

ROBERT DOES NOT PERSPIRE, SO WHEN HE GETS HOT, HIS TEMPERATURE GOES UP. IT WILL CONTINUE UPWARD UNLESS HE IS PLACED IN A COOL PLACE. AT 75-80 DEGREES, HIS TEMPERATURE WILL BE 100. HE WILL ALSO GET BLISTERS FROM HEAT OR FRICTION. EVEN IN A COOL ENVIRONMENT HIS TEMPERATURE WILL GO UP WITH EXERTION.

THIS SKIN CONDITION CAUSES ROBERT TO LOOK DIFFERENT. HIS SKIN DOES NOT ADHERE AS IT SHOULD, SO IT COMES OFF EASILY. ALSO, HIS SKIN REPRODUCES FASTER THAN NORMAL. THESE THINGS CAUSE SEVERAL PROBLEMS: (1) IF HE FALLS, THE SKIN COMES OFF EASILY. (2) IF HIT, THE SKIN MAY BLISTER OR COME OFF. (3) A REDUCED LEVEL OF

COORDINATION, CAUSED BY STIFFNESS OF THE JOINTS. (4) CLOTHING MUST BE EXTREMELY SOFT TO AVOID RUBBING FRICTION BLISTERS ON HIM.

DUE TO THE PROBLEMS MENTIONED ABOVE, ROBERT MAY DRESS DIFFERENTLY FROM SOME OTHER CHILDREN. HE HAS NEVER BEEN ABLE TO SIT FOR ANY LENGTH OF TIME WITHOUT A CUSHION---PRESSURE FROM HIS OWN WEIGHT CAUSES BLISTERS ON THE BACKS OF HIS LEGS. ALSO, SINCE THERE IS A BUILD-UP OF SKIN ON CERTAIN AREAS OF HIS BODY, THERE IS AN ODOR ASSOCIATED WITH THE CONDITION. THERE IS NOTHING THAT CAN BE DONE ABOUT THIS PROBLEM.

SINCE SEPTEMBER, 1982, ROBERT HAS HAD A STAPH INFECTION ON HIS SKIN. THIS IS A COMMON PROBLEM FOR CHILDREN WITH ROBERT'S CONDITION. HE IS ON A CONSTANT TREATMENT WITH ANTIBIOTICS, AND IS NOT CONTAGIOUS.

WE DESIRE THAT ROBERT BE ACCEPTED AS NORMALLY AS POSSIBLE BY HIS PEERS, AND ANY HELP YOU MAY GIVE HIM IN THAT REGARD WILL BE DEEPLY APPRECIATED.

IF ANY ADDITIONAL INFORMATION REGARDING ROBERT'S PROBLEM IS DESIRED, PLEASE DON'T HESITATE TO ASK HIM OR US ABOUT IT.

Attachment

"IT'S TIME TO PUT THE FOCUS ON ICHTHYOSIS"

Ichthyosis -- what is it? Ichthyosis is a term used to describe a group of hereditary disorders in which the outer horny layer of the skin is abnormal and has been likened in appearance to the skin of the lower vertebrates (fish, alligators, etc.) Many patients experience life-long disfigurement as well as considerable discomfort from the abnormal thickened horny layer. In addition, thermal regulation, water balance and growth and development may be adversely affected depending on the type and severity of the disease. Ichythosis is a rare disease with no known cause or cure, and although at least one in every 100,000 people suffer from it, it has received very little attention. There are many different forms of Ichthyosis, following are the four major ones:

(1) Lamellar Ichthyosis
Approximate rate of occurrence - 1 in 300,000

(2) Epidermalytic Hyperkeratosis
Approximate rate of occurrence - less than 1 in 300,000

(3) X-Linked Ichthyosis (males only)
Rate of occurrence - 1 in 6,000 males

(4) Ichthyosis Vulgaris (most common)
Rate of occurrence - 1 in 250

The National Ichthyosis Foundation is a new organization incorporated in the State of California as a non-profit, tax exempt organization on January 2, 1981. It is a voluntary organization which relies solely on contributions from the public to provide programs in education and research for the sufferers of Ichthyosis now and in the future. The Foundation is headed by a Board of Trustees consisting of both professional and lay people in the community, and a Medical Advisory Board composed of leading experts in the field of Ichthyosis, many of whom are actively engaged in research in this area.

The goals of the National Ichthyosis Foundation are:

(1) To help relieve the physical and mental distress among persons suffering from ichthyosis by providing practical advice, guidance and moral support.

(2) To distribute educational material about ichthyosis to the public and medical profession.

(3) To raise funds to promote and support scientific research into the causes, nature, treatment and cure of ichthyosis.

Ichthyosis is not a common disease, and the sufferers of Ichthyosis have not received any assistance from organizations supporting birth defects. It's time to put the focus on Ichthyosis! Now is the time to give the sufferers of this disease all the help we can; hopefully, it won't exist in the future. Please give us your support......thank you!

Senator WEICKER. Would you like to have Sarah and Robert say a few words at this juncture?

Ms. DEHAAN. I think that it would be appropriate.

Ms. MASSEY. My main problem in living with this, of course, is the heat factor. As you know, we sort of get tired of each other if we stay in the house for a week or two with other problems, but we stay in all summer, or we go from one air conditioned environment to another, because, like she said, there is no way to throw off the heat, so the temperature goes higher and higher, which, of course, could be a fatal problem if allowed to go on.

Also, he cannot go to local schools. He must find an air conditioned school. That is our main problem with it. At the moment, it is the heat factor, and then, of course, as she said, the heat friction causes problems—clothing, sitting for long periods of time.

Senator WEICKER. Robert, would you like to say something?

Robert MASSEY. No.

Senator WEICKER. Robert, what school do you go to?

Robert MASSEY. Woodmont Middle School.

Senator WEICKER. I imagine that both in the winter, when the heat is turned up, and in the summer when there is heat outside, that makes it tough on you.

Robert MASSEY. Yes.

Senator WEICKER. What do you like to do in the way of sports?

Robert MASSEY. Usually, if I get any outside time, when it is cool, I like to ride my bicycle, and swim some.

Senator WEICKER. That is great. That is what I did this morning for about an hour before I came to work, ride my bike.

Robert, you are here on behalf of a lot of other people, aren't you?

Robert MASSEY. Yes.

Senator WEICKER. Maybe Susan can tell us now as to exactly what it is that you look for as far as the budget is concerned.

Ms. DEHAAN. We are supporting the coalition's recommendation of $151,650,000. What we recognize is that there is a lot of need in the country, and there aren't the resources to go around. However, we do feel that this goes to the very quality of life and existence for some people. We have people who are dying from related kinds of problems with ichthyosis.

I have personal knowledge of some of the grants, and how the research is being done. I have seen it. I have been in the laboratories, and

I have seen the skin being grown. I feel that this is money that is being very well spent. With it being a very rare disease, there is no way that people with ichthyosis are going to be able to raise the funds to find cures for it themselves. So there is really a need to have some funding.

Senator WEICKER. I appreciate your being here.

Robert, it is just great having a handsome young fellow like yourself here.

Sarah, thank you for taking the time to come.

I can assure you that in our deliberations, we will make sure that there is some extra money put in to get on top of this.

Ms. MASSEY. We would appreciate it very much.

Senator WEICKER. Thank you very much.

STATEMENT OF WILL WACHTEL, REPRESENTATIVE TO PATIENT ADVOCATE COALITION FOR SKIN DISEASE RESEARCH, NATIONAL PSORIASIS FOUNDATION

Senator WEICKER. Next we will hear from Will Wachtel, representative to Patient Advocate Coalition for Skin Disease Research, the National Psoriasis Foundation.

Mr. WACHTEL. Mr. Chairman, and members of the subcommittee: My name is Will Wachtel. I am 33 years old, and I have had psoriasis since I was 17. I am here today as a volunteer on behalf of the National Psoriasis Foundation to request funding for the National Institute of Arthritis, Musculoskeletal and Skin Diseases at a level of at least $151 million. We believe that this amount is vitally needed to firmly establish this institute, and provide it with adequate staff, and most importantly to provide for research.

I am here with Ms. Gail Zimmerman, the executive director of the foundation. We are here on behalf of all psoriatics. It is estimated that there are 3 to 8 million Americans who have psoriasis. This equates to 1 in every 30 to 80 people.

Psoriasis is most easily characterized as producing too much skin. Normal skin cells replace themselves once a month, while psoriatic skin cells are supplanted in 3 days. I have the most common form of psoriasis which appears as reddish, elevated lesions.

Psoriasis can appear or worsen overnight and disappear or improve just as suddenly. It can strike anyone, though heredity is a factor, such as in my family. To me, a tragic fact is that psoriasis can occur at any age. I have seen photos of children and infants with psoriasis and it disturbs me greatly. Also tragic is the disability psoriasis causes. About 10 percent of psoriatics develop psoriatic arthritis. Other psoriatics are so severely covered with lesions that they are functionally disabled and, in a few cases, their lives are threatened.

We don't know exactly how many deaths are caused by psoriasis, but we do know this—it is an emotional killer, a life-destroyer. Since our skin is the means by which we initially define ourselves to others, coupled with the fact that we live in a society that places a high value on unflawed physical appearance, people with psoriasis feel uncertainty as to their acceptance.

I have made great leaps in my self-acceptance and worry less about how others react to me and yet I still will not wear short pants, sunbathe, or swim in public. Over the last few years, concealed parts of my body have cleared while my facial psoriasis has spread. Every day people stare at me and usually I can deal with it, but when it is really noticeable, it takes great effort to overcome my self-consciousness and leave my house.

I am perturbed that most of the public perception is limited to parodies of "the heartbreak of psoriasis," yet many haven't seen it and they react with the fear of catching it. It is not contagious, but since they don't know that, they shy away. Also, one of the hardest things for psoriatics to face is that there is no cure.

If I have painted a grim picture, I regret that. But there is hope for psoriatics. Thanks to your previous support, we know much more about psoriasis because the NIH has been the main impetus of psoriasis research in the United States. The NIH was responsible for developing a therapy called PUVA, one of the most effective treatments available today. Additionally, the NIH has done work on etretinate, a new experimental drug that is producing results.

With the new institute, there is an opportunity to achieve greater successes. By its creation, Congress has intended that these diseases receive increased emphasis. We are asking you to carry this intention into reality by appropriating a minimum of $151 million. The past support of scientific research has enabled this country to make tremendous medical advances. Now we need to send a message to researchers that we will continue to support their commitment to helping the Nation. Please send this message.

Thank you for your time and consideration of our request. I guarantee you that you have made and can make a difference in the lives of those of us who are afflicted with psoriasis.

PREPARED STATEMENT

Senator PROXMIRE [presiding]. Thank you very much, Mr. Wachtel. You gave a very moving presentation, and we deeply appreciate it. You are requesting a very large increase, as you know, percentage-wise, and these are very, very tough times to get increases anywhere, although you certainly make an extremely strong case for a worthy purpose. Thank you very much.

Mr. WACHTEL. Thank you.

[The statement follows:]

STATEMENT OF WILL WACHTEL

My name is Will Wachtel. I am 33 years old and I have had psoriasis since I was 17. I am here today as a volunteer on behalf of the National Psoriasis Foundation to request funding for the new National Institute of Arthritis, Musculoskeletal and Skin Diseases at a level of at least $151,000,000. We believe that this amount is vitally needed to firmly establish this Institute with adequate staff and, most importantly, to provide for research.

I am here with Ms. Gail Zimmerman, Executive Director of the Foundation, and we are here on behalf of all psoriatics. It is estimated that there are 3-8 million Americans who have psoriasis. This equates to 1 in every 30 to 80 people.

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Thank you for your time and consideration of our request. I guarantee you that you have made and can make a difference in the lives of those of us afflicted with psoriasis.

STATEMENT OF PEYTON E. WEARY, M.D., WASHINGTON REPRESENTATIVE, COUNCIL ON GOVERNMENTAL LIAISON, NATIONAL ACADEMY OF DERMATOLOGY

Senator PROXMIRE. Our next witness is Dr. Peyton Weary. Dr. Weary is the Washington representative of the Council on Government Liaison of the American Academy of Dermatology.

Dr. Weary, we are delighted to have you here.

Dr. WEARY. Thank you, Senator. It is a pleasure to be here.

I would like to, before I start, mention that I heard the testimony from Susan about ichthyosis from the Ichthyosis Foundation. I would emphasize for you the importance of this disease. I happen to have a daughter with this, who has the most severe type of ichthyosis. It is an extremely disfiguring and difficult disease to live with. I would reinforce the statement that she made about this important disease.

I am delighted to be here. You were not here earlier Senator when Senator Hatfield asked about the number of good grants in skin disease research. I am very pleased to tell you that skin disease research is alive and well.

Later this week, the Society for Dermatology will be meeting here in Washington. At that time, there will be 157 papers presented at that meeting, and 64 posters, each of which will be devoted to some independent research in one or another skin disease.

So it is very good. There is a tremendous ferment, a tremendous opportunity for advancement in this area, and we are excited. We are very excited about the fact that we have this new institute and we are delighted to come here and testify on behalf of and in support of this new institute.

We think that it is essential that this whole new venture receive adequate support in its fledgling year, which is consistent with the wishes of the Congress in establishing the new institute. We very strongly support the coalition budget of $151,650,000.

We feel that this sum would establish pay lines of 170 in contrast to the projected pay lines of only 150 under the President's proposed budget. It would also provide an award rate of 34 percent in contrast to the projected 24 percent under the President's proposed budget, which we think is unacceptably low.

We have also heard previously from people at the NIH that if the President's budget is adopted, there would be a need to cut grant support in the NIAMS by 16 to 18 percent across the board for fiscal year 1987 in contrast to the current 11 percent cut for fiscal year 1986.

There are data, Senator, which show clearly what such cuts do to the productivity of research. We have grave concern about what they do. We recognize the need to be frugal, but we also recognize that there is a point beyond which cutting will cease to be simply frugal, and significantly reduce the productivity of our biomedical research.

We have great concern about increasing this across the board cut any more than the 11 percent that is currently existing.

We also note with concern the efforts of the Office of Management and Budget to impose arbitrary ceilings on indirect research cost reimbursement, and feel that this two-pronged assault on biomedical research that is being launched by the administration may prove ultimately to be very counterproductive for all biomedical research.

We have been told furthermore that under the President's proposed budget, the number of new grants from the new institute would be reduced from a projected number of 199 in 1986 to only 148 in fiscal year 1987, and that existing grants would fall from a figure of 582 projected for 1986 to 537 for for 1987.

We think that this is most disturbing and clearly in conflict with the congressional intent to stimulate more and not less research in diseases that come under the purview of this institute, this new institute, which have been so disabling and disfiguring for individuals for so many centuries.

We also, in our written testimony, direct your attention to the other institutes which we have testified on behalf of in the past, and there are a number of them, in particular the Cancer Institute which has our intramural program within it. It is a superb intramural program, and it is a wonderful place where new research people in dermatology are being trained constantly.

We also feel that it is important that this institute also be well-supported because we have a major drive right now to make the public aware of the importance of skin cancer, and in particular melanoma. The type of research that is being done in the Cancer Institute will supplement our efforts in this behalf.

We also direct your attention to what we feel is inadequate support for the National Institute for Occupational Safety and Health, which has been poorly supported, yet we recognize the fact that occupational skin diseases are a major problem in our society, leading to much reduction in productivity among workers.

I thank you very much for the opportunity to present this testimony to you, Senator.

Senator PROXMIRE. Dr. Weary, I understand that under the administration's budget new grants would fall from 199 currently to 148 next year.

Dr. WEARY. Yes, sir.

Senator PROXMIRE. How many new grants would be supported under your proposed budget?

Dr. WEARY. The proposed budget in the coalition document that you have there, we would project an award rate of 34 percent, a pay line of 170, and 223 new grants in fiscal year

Senator PROXMIRE. Thank you for an excellent presentation.

Dr. WEARY. Thank you very much, Senator.

STATEMENT OF MARY KAYE RICHTER, EXECUTIVE DIRECTOR, NATIONAL FOUNDATION FOR ECTODERMAL DYSPLASIAS

Senator PROXMIRE. Our next witness is Mary Kaye Richter, executive director of the National Foundation for Ectodermal Dysplasias.

Ms. RICHTER. It is a long way from the corn fields of southern Illinois, but still it is a great pleasure to be here.

Senator PROXMIRE. It is not a long way from the corn fields of Illinois to the dairyland of Wisconsin.

Ms. RICHTER. That is right. I am going to spend some time there this summer.

At any rate, my name is Mary Kaye Richter. I serve as executive director of the National Foundation for Ectodermal Dysplasias, which is based in Mascoutah, IL. I am here today to talk to you about the budget for the National Institute of Arthritis, Musculoskeletal and Skin Diseases.

Although I have a great interest in the funding for that particular organization, I think that it is more important for me to spend time today discussing why that funding is so necessary.

In retrospect, my life of 8 years ago was idyllic. Farming was enjoying an era of prosperity, and I had been blessed with two healthy children, and a life unconcerned with national programs, policies, or direction.

Since that time, however, things have changed greatly, as you might suspect, certainly among those was the birth of a son with an unusual birth defect known as ectodermal dysplasia [ED]. With my return from what I call a cocoon of citizen ignorance, I now have come to have great respect for what the Congress has done in regard to the national health for the citizens of this country, and for that, I give you great thanks.

The National Foundation for Ectodermal Dysplasias is a nonprofit organization committed to assisting individuals affected by an ectodermal dysplasia syndrome, their families, and professionals who provide care. More important are our activities to provide information on the syndromes and to assist families affected by ED in coping with the problems of living with these unusual disorders.

The ectodermal dysplasias are a group of genetic disorders encompassing at least 117 individual syndromes. Each of these syndromes is identified by two or more derivatives of the ectoderm which do not function appropriately. All too often, when the term "skin disorders" is heard, people think only of acne and poison ivy. However, the ectodermal dysplasias and other skin disorders which you have heard about today severely alter the lives of their victims.

The patients we represent include those affected by a myriad of medical difficulties. There are those with an inability to perspire. I might say, it occurred to me as I was sitting in the room, that this perhaps would be a good place to get a cure for that inability to perspire because sweaty palms come easily.

The problems, though, of that inability to perspire can lead to extremely high body temperatures, which may result in paralysis or brain damage, and eventually death. Nearly 25 percent of the families we serve have lost children in their infancy.

Other difficulties for our patients include sparse hair, absence of teeth, hearing and sight deficiencies, significant respiratory infections, missing limbs, dysfunction of certain glands such as those producing tears and saliva.

All of these problems are a direct result of malfunctions in the ectoderm. Life for these individuals so affected are altered by an inability to attend school, to participate in activities, or to work in occupations where temperatures can be a factor.

The need for treatment for the skin and mouth is continuous. Although the disorders have been documented prior to the time of Darwin, virtually nothing is known about how they happen, or the type of medical and dental care that would best meet the needs of these patients.

For parents, the birth of a child affected by a relatively rare disorder is immensely traumatic. This is compounded when you quickly learn that even on a professional level, little information is available, let alone treatment. How then can we have hope?

The establishment of the Institute of Arthritis, Musculoskeletal and Skin Diseases is our best hope since ectodermal dysplasias and other related skin disorders were first identified. I am not so naive as to believe that with the development of this institute that miraculous discoveries about ectodermal dysplasias or other specific skin disorders will occur overnight. What I do believe is that with sufficient funding for basic skin research, this institute will yield results which will greatly enhance the chances for spinoff benefits.

Furthermore, with the increased awareness that this emphasis suggests, those affected by skin disorders will ultimately receive earlier diagnosis, improved information, and treatment.

Foremost in my present thoughts are a concern for the level at which the NIAMS will be funded. Millions of Americans are affected by skin disorders. The costs for treating these disorders alone must be staggering and when added to the expenses of lost wages and productivity, disability and workers compensation payments and increased social service expenditure, we find ourselves burdened by billions of dollars of costs for these disorders.

My own family can expect to pay at least $40,000 in treatment costs for our son affected by ED by the time he reaches his 18th birthday, and that does not include any hospitalization costs which may arise. Placing this Institute among the Nation's highest priorities will in the longrun serve as a credit rather than a debit to the Nation's fiscal management.

Great advances in medical technology have to begin somewhere. Without research, the menace of polio would still be with us, the door to the understanding of DNA would still be locked, and the rejuvenation of the body through organ transplants would not be possible. Certainly these represent only a fragment of the medical advancements that have been made possible in recent years.

But the point here is that they had to begin with research and sufficient funding to make that research possible. For those individuals affected by skin disorders research remains as the only hope for a chance at not only a normal lifespan, but also for a nearly normal lifestyle. It is moral responsibility to see that those persons affected by epidermolysis bullosa, ichthyosis, alopecia areata, psoriasis, ectodermal dysplasia, and other skin disorders have their chance for medical miracles.

I am a farm wife. Right now, I know what balancing budgets means all too well. I am also the executive director of a nonprofit foundation that exists on its own depending upon individual and group donations for its lifeblood. But through my various liferoles, I have learned an important fact—all that is, where there is a will there is a way.

If you share our concerns for the health of those suffering and dying from skin disorders, you will help pave the way for a brighter future. Certainly, the first and perhaps most important step is the funding of the NIAMS at sufficient levels as to encourage research into basic skin science and research on skin disorders. My hope is that one day, I may return here to express my appreciation to you for the elimination of some skin diseases, breakthroughs in others, and hope for those that remain.

PREPARED STATEMENT

A caterpillar ambling through verdant grass looked up to see a glorious butterfly drifting along on a gentle breeze. The caterpillar thought to himself, "you will never get me up in one of those things." Fortunately, not all caterpillars see life quite that way. With the development of NIAMS, we have but a caterpillar, please provide the funding which will permit it to soar.

I thank you for this chance to be here.

[The statement follows:]

STATEMENT OF MARY KAYE RICHTER

Good Morning! My name is Mary Kaye Richter. I serve as the executive director of the National Foundation for Ectodermal Dysplasias based in Mascoutah, Illinois. I must admit that having the opportunity to participate in this proceeding is an enormous thrill for this farm wife from southern Illinois. Eight years ago I would never have anticipated doing such a thing but the birth of our youngest son has brought many changes and new experiences to my life.

In retrospect, my life of eight years ago was idyllic. Farming was enjoying an era of prosperity, I had been blessed with two healthy children and a life unconcerned with national programs, policies, or direction. Although that period of time was less stressful, the unfortunate changes in my life have left me with, among other things, great respect for the action of our Congress. You have my deep appreciation for the work of agencies like the National Institutes of Health, whose efforts you oversee. Where I was once blissfully unaware of such activities, I have emerged from the cocoon of citizen ignorance and apathy and appear before you today to discuss the National Institute of Arthritis, Musculoskeletal, and Skin Diseases.

The National Foundation for Ectodermal Dysplasias is a non-profit organization committed to assisting individuals affected by an ectodermal dysplasia syndrome, their families, and professionals who provide care. Most important are our activities to provide information on the syndromes and to assist families affected by ED in coping with the problems of living with these unusual disorders.

The Ectodermal Dysplasias are a group of genetic disorders encompassing at least one hundred and seventeen individual syndromes. Each syndrome is identified by two or more derivatives of the ectoderm which do not function or have diminished function. When the term skin disorders is mentioned it is all to easy to think only of acne and poison ivy. The ectodermal dysplasias and other skin disorders severly alter the lives of their victims. The patients we represent include those affected by a myriad of medical difficulties. Those with an inability to perspire may experience extremely high body temperatures which may result in parallysis, brain damage, or death. Nearly twenty-five percent of the families we serve have lost children in their infantcy. Other difficulties include sparse hair, absence of teeth, hearing and sight deficiencies, significant respiratory infections, missing limbs, and dysfunction of certain glands such as those producing tears or saliva. All of these problems are a direct result of malfunctions in the ectoderm. Life for those individuals so affected is altered by an inability to attend school, to participate in activities, or to work in occupations where temperature could be a factor. The need for treatment for the skin and mouth is continuous. Although the disorders have been documented prior to the time of Darwin, virtually nothing is known about how they happen or the type of medical/dental care which would best meet the needs of the patient. For parents, the birth of a child affected by a relatively rare disorder is immensely traumatic. This is compounded when you quickly learn that even on the professional level little information is available let alone treatment. How then can we have hope?

The establishment of the National Institute of Arthritis, Musculoskeletal, and Skin Diseases is our best hope since ectodermal dysplasia and other related skin disorders were first identified. I am not so naive as to believe that with the development of this Institute that miraculous discoveries about ectodermal dysplasias or other specific skin disorders will occur over night. What I do believe is that with sufficient funding for basic skin research this Institute will yield results which will greatly enhance the chances for spin-off benefits. Furthermore, with the increased awareness that this emphasis suggests, those affected by skin disorders will ultimately receive earlier diagnosis, improved information and treatment. Foremost in my present thoughts are a concern for the level at which the NIAMS will be funded. Millions of Americans are affected by skin disorders. The costs for treating these disorders alone must be staggering and when added to the expenses of lost wages and productivity, disability and workers compensation payments and increased social service expenditure we find ourselves burdened by billions of dollars of costs for these disorders. My own family can expect to pay at least $40,000 in treatment costs for our son affected by ED by the time he reaches his 18th birthday--and that does not include any hospitalization costs which may arise. Placing this Institute among the nation's highest priorities will in the long run serve as a credit rather than as a debit to the nation's fiscal management.

Great advances in medical technology have to begin somewhere. Without research the menace of polio would still be with us, the door to the understanding of DNA would still be locked, and the rejuvenation of the body through organ transplants would not be possible. Certainly these represent only a fragment of the medical advancements that have been made possible in recent years. But the point here is that they had to begin with research and sufficient funding to make that research possible. For those individuals affected by skin disorders research remains as the only hope for a chance at not only a normal life span but also for a nearly normal life style. It is our moral responsibility to see that those persons affected by epidermolysis bullosa, icthyosis, alopecia areata, psoriasis, ectodermal dysplasias, and other skin disorders have their chance for medical miracles.

I am a farm wife. I know what balancing budgets means all to well. I am the executive director of a non-profit foundation that exists on its own depending upon individual and group donations for its life-blood. But throught my various life roles I have learned an important fact--and that is, where there is a will, there is a way. If you share our concerns for the health of those suffering and dying from skin disorders you will help pave the way for a brighter future. Certainly, the first and perhaps most important step is the funding of the NIAMS at sufficient levels as to encourage research into basic skin science and research on skin disorders. My hope is that one day I may return here to express my appreciation to you for the elimination of some skin diseases, breakthroughs in others, and hope for those that remain.

A caterpillar ambling through verdant grass looked up to see a glorious butterfly drifting along on a gentle breeze. The caterpillar thought to himself, "you'll never get me up in one of those things". Fortunately not all caterpillars see life quite that way. With the development of NIAMS we have but a caterpillar, please provide the funding which will permit it to soar.

Thank you for this special opportunity to express my views.

Senator PROXMIRE. Thank you, and thank you for that beautiful analogy. That is a surprise coming from Caterpillar Tractor country. [Laughter.]

You say that your own family expects to pay $40,000 for your son's medical care by his 18th birthday.

Ms. RICHTER. That is right, and the bulk of that will either be for skin care or for dental care.

Senator PROXMIRE. Do you have to pay those costs yourself?

Ms. RICHTER. Absolutely. It is interesting in that these children are born without teeth, or are missing most of their teeth. Most insurance policies have dental exclusions on them, and they don't consider this a birth defect, they just consider it a dental problem, so the need to pay for those dentures rests with the families.

My son received some dentures about every 18 months. My hope is that as he gets older, he can have a procedure done which is called titanium ossio-integrated implants. That surgery alone is almost $20,000, and here again that is borne by the families involved. It is a very difficult situation, one that we all think is very unfair.

Senator PROXMIRE. Of course, as big as that financial burden is, it is the least of your problems. There is also great pain and difficulty for your son, and difficulty for you, too.

Ms. RICHTER. Absolutely. At this point, I feel fortunate in that my son was not diagnosed until he was 18-months old, and he had many, many high fevers. I realize now that I am dealing with other families that a lot of these children simply die, and people don't understand why. So I am fortunate that he has survived at that point. I hope that with the facial or the body presence that he makes will not so affect his self-esteem that he will be able to go ahead with life, and do well.

Senator PROXMIRE. Do you have any idea how much is being spent currently on research into ectodermal dysplasias, and how much would be spent next year under the administration's proposal?

Ms. RICHTER. Right now, there is absolutely nothing being spent on ectodermal dysplasias, period, and there is nothing budgeted. My concern here is that if the Skin Institute is funded at a level which will allow the various grants that Dr. Weary alluded to earlier, perhaps some of these grants will allow for research into the ectodermal dysplasias.

Senator PROXMIRE. Thank you very much.

Ms. RICHTER. Thank you.

STATEMENT OF RALPH SNYDERMAN, M.D., MEMBER, NATIONAL ARTHRITIS ADVISORY BOARD

ACCOMPANIED BY MAUREEN DRUMMY, VICTIM

Senator PROXMIRE. Our next witness is Dr. Ralph Snyderman, a member of the National Arthritis Advisory Board.

Dr. Snyderman, we are happy to have you with us.

Dr. SNYDERMAN. Senator Proxmire, thank you for letting me speak to you today. Ms. Drummy is one of your constituents.

Senator PROXMIRE. Are you from Wisconsin?

Ms. DRUMMY. Yes, indeed.

Senator PROXMIRE. No wonder you are so good looking. Where do you live in Wisconsin?

Ms. DRUMMY. Waupun. I was Congressman Bill Steiger's administrative assistant.

Senator PROXMIRE. He was a marvellous Congressman, and we miss him very much. His wife is still in town.

Dr. SNYDERMAN. Senator, thank you for letting me speak to you today. I am Ralph Snyderman, chief of the Division of Rheumatology and Immunology at Duke University Medical Center. I speak to you today as chairman of the Research Committee of the National Arthritis Advisory Board.

As you are probably aware, diseases of the joints and connective tissues affect approximately 35 million Americans. Greater than 1 in 10 of all of our people suffer from some type of connective tissue disease.

The incidence of chronic juvenile arthritis, arthritis which frequently leads to crippling of children, affects roughly a quarter of a million of our population, and this number is actually higher than the highest incidence of paralytic poliomyelitis during the most severe epidemics of the past.

The cost each year of hospital care, professional services and drugs for arthritis and the loss of productivity from arthritis is estimated at $18.6 billion.

In 1976, Congress enacted Public Law 94-562, which established the National Arthritis Advisory Board. The Board's purpose is to supervise and report on the implementation of the arthritis plan. My testimony is based in part on the Board's findings and recommendations.

As you are aware, there have been tremendous advances in biomedical technology. The field of biomedical research is undergoing a virtual explosion. The possibilities of further progress with direct application into therapy of arthritic disease is great, but we need to do a great deal to try to translate this potential into actual practice.

What I would like to mention very briefly is what are the research efforts that are focusing on arthritis, and these fall into three broad categories. One, primarily basic research dealing with the field of immunoregulation, the immune system which is vital to protect us against severe diseases, such as we are seeing in patients with AIDS, to protect us against cancer, and when directed against tissues in your own body can cause severe diseases, such as rheumatoid arthritis.

The National Institutes of Health is funding a considerable amount of research into understanding how the immune system works and how to regulate it. There is also considerable research into the area of connective tissues, and specific rheumatic diseases such as rheumatoid arthritis, osteoarthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, gout, osteoporosis, and many heritable disorders.

Progress in these areas has been considerable in rheumatoid arthritis. Several infectious agents have been identified in the past few years, virus such as the parvovirus and the Epstein-Barr virus, which is responsible for mononucleosis, and may play a role in some genetically susceptible individuals for the development of rheumatoid arthritis.

In the field of osteoarthritis, by far the most common form affecting 16 million people, a great understanding of the mechanisms of the initiation of this type of disease has occurred in the past year.

Ms. Drummy is a very good example of advances in reconstructive surgery. Several years ago, she would have had to come to the table using crutches, and now she is able to walk very well on her own.

Systemic lupus erythematosus is another very severe disease. Major progress has been made in this area as well in the past year in understanding of dietary manipulation as a potential treatment for this is receiving a lot of attention.

The National Arthritis Advisory Board is encouraged by these accomplishments and wants to support further efforts in this area. We feel that funding of arthritis related research needs to be focused in these following areas, which I will go over very briefly.

Individual research grants—investigator initiated research grants are the backbone of our biomedical research environment. It is absolutely essential that we fund individual research grants at a higher level than we are now. I am a practicing biomedical researcher at Duke, and I could tell you that the large wave of people into this field that occurred in the late 1960's and early 1970's is contracting, and younger investigators are very insecure about the potential for further funding. The rate of grants being awarded has fallen from 45 percent to 25 percent, and perhaps lower. I think that this needs to be brought back up with the goal of coming to 45 percent again.

The most important initiative of the National Arthritis Advisory Board is to develop specialized centers of research in the area of the rheumatic and arthritic diseases. We feel that this would be essential to translate the power of the biomedical technology to the field of arthritis and arthritis related diseases.

If I can emphasize one point to you this morning, it is the institution of special centers of research in the area of arthritis is extremely important. We would like to focus on three major diseases: rheumatoid arthritis, osteoarthritis, and osteoporosis.

Finally, funding for arthritis research manpower is vital, and we need to continue funding for institutional training grants which have been cut tremendously in recent years.

Finally, with the establishment of the National Institute of Arthritis, Musculoskeletal and Skin Diseases, which you already heard about so eloquently from other speakers, the Board recommends that some specific funding for the administration of this new institute be provided. I specifically recommend that approximately $3.5 million be appropriated for the administration of this new institute so that it can get started.

PREPARED STATEMENT

Thank you very much for allowing me to present our views.

[The statement follows:]

STATEMENT OF RALPH SNYDERMAN

I am Ralph Snyderman, Chief of the Division of Rheumatology and Immunology, Department of Medicine at Duke University Medical Center and Chairman of the Research Committee, National Arthritis Advisory Board. I appreciate the opportunity to appear before you to present the recommendations of the National Arthritis Advisory Board.

Disorders of the joints and connective tissues afflict more than 35 million Americans, or 1 in 7 of all our people. More than 120 different disorders of the joints and connective tissues are categorized under the broad term "arthritis," a group of chronic diseases that is the Nation's leading crippler. Although the prevalence of arthritis is higher among older persons, an estimated 250,000 children have juvenile arthritis, which, in addition to causing pain and swelling of the joints, can retard growth and lead to early blindness, kidney disease, or death. Arthritis in children is, in fact, more prevalent than was paralytic poliomyelitis during the most severe epidemics of the past. Most forms of arthritis are chronic, and many patients unfortunately require lifelong medical care. The cost each year of hospital care, professional services and drugs for arthritis and the loss of productivity from arthritis is estimated at $18.6 billion.

In 1976, Congress enacted P.L. 94-562, which formally established the National Arthritis Advisory Board. The Board's purpose is to monitor the implementation of the Arthritis Plan, to recommend any changes in the Plan, and to propose to Congress and the Administration appropriate guidelines, policies, and procedures for Federal programs relating to arthritis. Our most recent annual report will be provided to the subcommittee today. My testimony is based upon the Board's findings and recommendations.

Advances in fundamental science are contributing to an improved knowledge of the disease processes and mechanisms of arthritis. A great deal of progress has been made in understanding these chronic, crippling disorders. Some of these diseases now can be partially controlled with medication and other types of therapy.

The research effort in arthritis encompasses three general areas: projects associated with immune disregulation, autoimmune diseases, rheumatoid factor, antigen-antibody reactions, and immune complex formation; research concerned with the structure and function of connective tissues such as collagen, basement membranes, synovial tissues, and articular cartilage damaged in the rheumatic diseases; and research projects in specific rheumatic diseases (rheumatoid arthritis, degenerative joint diseases, juvenile arthritis, systemic lupus erythematosus, gout, osteoporosis, and heritable disorders). A fourth related area of basic and clinical research involves the study of the musculoskeletal system in normal and diseased conditions.

Specific agents recently have been found that may initiate or trigger rheumatoid arthritis; these include infectious agents such as parvovirus and Epstein-Barr virus. Moreover, only certain persons who are susceptible to rheumatoid arthritis by their genetically determined immune responsiveness appear to develop the chronic and active inflammation of rheumatoid arthritis. Research on newly developed animal models of arthritis is enhancing the scientific knowledge of these diseases.

Osteoarthritis, the most common form of arthritis, affects 16 million people in the United States. One of the most disabling and crippling diseases in older populations, it has been a difficult disease to study. Two recent research developments point to possible advances in our knowledge of osteoarthritis. In the first, biochemical observations indicate that cartilage cells produce the substances that both build and destroy the cartilage; this may lead to an understanding of why damaged cartilage is unable to repair itself and may help in discovering new ways to induce this repair. In the second development, several new experimental models of osteoarthritis offer the hope for greater knowledge of the cause of and new treatments for this disabling disorder.

Remarkable advances in reconstructive surgery for osteoarthritis and rheumatoid arthritis have been made during the past decade. Improvements have been achieved in total joint replacements for severely damaged hips, knees, shoulders, elbows, and wrists. These results have been achieved through the combined research efforts of bioengineers, rheumatologists, materials scientists, and orthopedic surgeons. Loosening of the joint implant after several years remains a problem. Nonetheless, the future holds promise for the development of implants that will provide normal joint function over an indefinite period.

Systemic lupus erythematosus (SLE) is a serious inflammatory connective tissue disorder that involves many organ systems. Research on SLE, a condition that primarily affects young women, continues to be active and productive. More is being discovered about abnormal immunoregulation in SLE; for example, a newly identified defect in complement receptors on cells in lupus patients may be inherited. Dietary manipulation can alter SLE in experimental models in inbred mice; nonsaturated fatty acids may inhibit the disease-producing immune reactions in these SLE mice. Hormonal regulation also has been shown to be important in SLE and may explain the predominance of SLE in women.

The research potential is considerable for scleroderma, a serious connective tissue disease, and for the spondylitic (spinal arthritis) group of rheumatic diseases, such as ankylosing spondylitis (AS), Reiter's syndrome, psoriatic arthritis, and the gout-associated arthropathies. The Board believes that research in all arthritis-related diseases is at a critical point for major breakthroughs. New leads are emerging in many areas of investigation. Moreover, the availability of new biomedical research technologies such as monoclonal antibodies, recombinant DNA, molecular genetics, and computers is accelerating the pace of major scientific discoveries, yet needs to be exploited more fully.

The National Arthritis Advisory Board is encouraged by the accomplishments of research into the causes and mechanisms of arthritis and the development of new devices, surgical techniques, and drugs that are used to treat arthritis patients. These accomplishments result largely from the impetus generated by the Arthritis Plan that was developed by the National Commission on Arthritis and Related Musculoskeletal Diseases in 1976. The plan identified the major needs and opportunities in arthritis research and treatment and led to a modest increase in Federal appropriations for arthritis-related projects. However, the base of support for scientific investigation has been reduced in recent years because appropriations have not kept pace with the increased cost of biomedical research. Therefore, the research advances we have seen in the past decade are not likely to be duplicated in the future unless additional resources are provided. This reduction in the research base is a major concern to the Board, especially in light of the new and promising opportunities for progress in the prevention, early diagnosis, and treatment of arthritis.

Congress and the administration share the Board's concern about the impact of arthritis on the Nation. In 1985, the Secretary of Health and Human Services identified arthritis research as a departmental priority initiative and Congress authorized the establishment of a separate National Institute of Arthritis, and Musculoskeletal and Skin Diseases (NIAMS) in P.L. 99-158. These actions have laid the foundation for the growth of arthritis-related research programs. However, additional funds must be appropriated before the promise of 1985 can become a reality in 1986 and in the future.

To continue this important program, the appropriation for NIAMS must be increased in fiscal year 1987 and subsequent years. The Board has carefully considered the resources required for the above programs and recommends a total budget of $178.4 million for fiscal year 1987. This recommendation includes funds for the following:

Individual Research Grants: The percentage of approved grants for arthritis and related research projects that can be funded has declined steadily from about 45 percent a few years ago to approximately 25 percent in fiscal year 1985. In fiscal year 1986, this rate will drop even farther under current budget allocations. The Board's recommendations would restore the award rate to approximately 45 percent of approved grants.

Specialized Centers of Research (SCORs): One of the most important initiatives of the Board this year is to obtain Congressional support to establish SCORs in the field of arthritis and related diseases. This special research mechanism has been extremely effective in disease areas supported by the National Heart, Lung, and Blood Institute. The Board is convinced that the establishment of Specialized Centers of Research will provide an extraordinarily effective means of concentrating research personnel and resources on three initial areas of priority and opportunity: rheumatoid arthritis, osteoarthritis, and osteoporosis. SCORs are multidisciplinary, having both basic science and clinical research emphasis, ensuring that advances in basic science are rapidly translated into clinical application, and that clinical needs provide the direction for the basic science. The major recent advances in biomedical technology, as exemplified by the field of molecular biology, need to be rapidly applied to research dealing with arthritis-related diseases. SCOR programs provide an important addition to investigator-initiated research projects, and will spur rapid application of new biotechnological techniques to arthritis research.

In its report on the fiscal year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations stated that SCORs "are useful mechanisms for accelerating research in areas where coordinated, multidisciplinary efforts are likely to produce rapid clinical applications of basic science advances." The Committee requested the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases to prepare an assessment of the scientific feasibility and potential benefit of establishing SCORs in arthritis and related diseases. The resulting assessment clearly indicates that the SCOR mechanism would be a valuable adjunct to existing research programs in this area. The Board's recommendations include funds to establish 9 SCORs in 1987, three each in the areas of rheumatoid arthritis, osteoarthritis, and osteoporosis.

Arthritis Research Manpower: The Board also is concerned about the lack of adequate funds for the development of future research scientists. Three different types of individual career development awards are used to support arthritis and related research. The Clinical Investigator Award and the Physician Scientist Award are key to providing adequate opportunity for M.D.'s to acquire sufficient research training and experience in modern methods of biomedical technology to become qualified as independent investigators. The Research Career Development Award enables young established investigators, either M.D.'s or Ph.D.'s, to devote themselves entirely to research during a crucial state of career development. The budget for all these three awards has become so restricted that we anticipate a very severe decline in capacity to support current and future candidates. Funds for institutional training grants also have been severely restricted in recent years, leading to a steady decline in the number of young investigators selecting a research career. The Board's budget recommendations include additional funds to support these vital programs. The national investment in biomedical research manpower needs to be maintained and fully supported.

Establishment of the National Institute of Arthritis, Musculoskeletal, and Skin Diseases: The creation of this new institute, authorized by P.L. 99-158, will require additional personnel positions and associated funds for essential administrative and scientific functions. The need for these resources was well documented by the sponsors of the enabling legislation. Neither the funds nor the positions have been provided. The Board recommends that 36 additional positions be provided and $3.5 million be appropriated for this purpose.

The Board appreciates your support for arthritis research and the opportunity to appear before this Subcommittee. I will be pleased to respond to any questions you may have.

Senator PROXMIRE. Thank you, Dr. Snyderman. I thank you very, very much. You certainly have a fine example of what can be done with you.

I noticed a minor arithmatical error. You said at the outset that 35 million Americans, or more than 1 in 10 suffer from arthritis; 1 in 7 is the correct figure.

Dr. SNYDERMAN. That is correct.

Senator PROXMIRE. I was afraid that you were getting like the minister who made an impassioned plea for his congregation to donate at least one-tenth of their income. When he finished the plea, he was so impassioned that somebody in the back row said, "Reverend, one-tenth is not enough. We should donate one-twentieth." [Laughter.]

My office has received a lot of mail, and I think other congressional offices have too, over the years regarding a controversial arthritis therapy involving the use of tetracycline. Does this treatment modality hold out any hope, and is it being explored?

Dr. SNYDERMAN. The use of tetracycline for the treatment of rheumatoid arthritis has been quite popular, particularly in the Washington, DC, area, under a team of Dr. Brown who is the leading exponent of this.

The National Institutes of Health is aware of individuals who have contributed by Dr. Brown and who have reported very favorable results.

As far as I am aware, having spoken to Dr. Shulman, who is the acting director of the new institute, specific trials are going to be instituted, and negotiations are ongoing with Dr. Brown.

I would say, at present, this has still not proven to be an effective therapy, but considering the interest in infectious agents in the etiology of rheumatoid arthritis, it certainly is a plausible form of therapy, but it needs to be proven, however.

Senator PROXMIRE. Thank you very, very much.

We are graced with the presence of the chairman of the full committee, Senator Hatfield. I understand that Senator Hatfield has a witness he would like to call.

Thank you, Dr. Snyderman.

Dr. SNYDERMAN. Thank you, Senator.

STATEMENT OF GERARD MOSELEY, PH.D., VICE PROVOST OF STUDENT AFFAIRS, UNIVERSITY OF OREGON, ON BEHALF OF THE POLYCYSTIC KIDNEY RESEARCH FOUNDATION

Senator PROXMIRE. The next witness will be Dr. Gerard Moseley. We have mispelled your first name, Doctor. If you were from Wisconsin rather than from Oregon, I would know better. You are the vice provost of student affairs at the University of Oregon, and you are appearing on behalf of the Polycystic Kidney Research Foundation.

Dr. MOSELEY. I can't blame you for that, because I graduated from high school before I actually realized that my name was Gerard instead of Jerry. [Laughter.]

Senator HATFIELD. Mr. Chairman, I am very happy to welcome Dr. Moseley here today.

Do you have your son with you today?

Dr. MOSELEY. Yes; in fact, David is over here snapping your picture. I would like to introduce David.

Senator PROXMIRE. Stand up, David, it is good to see you.

Senator HATFIELD. I am very happy to welcome both of you here.

Mr. Chairman, I only came to not only welcome Dr. Moseley, but to indicate that he comes to us in an interesting capacity today, not only as a distinguished administrator at the University of Oregon and a scientist, but he is here as a citizen because of the difficulty that he and his family have experienced from this kidney problem.

He comes in a very informed capacity, and I am delighted to have him here this morning.

Dr. MOSELEY. Senator Hatfield, thank you very much, and Senator Proxmire.

My name is Gerard Moseley. I am from the University of Oregon, the vice provost for student affairs. I am actually, as Senator Hatfield indicated, not in the medical field. I am a layman here this morning. In fact, thinking about it, being an astronomer, a radio astronomer at that, I really feel out of place here, except to note that there are a lot of things in colleges and universities that we have to deal with.

My reason for being here is that in the last year or so, I have really become interested in educating myself about the problems of polycystic kidney disease first-hand.

All my life, beginning when I was 30 years old, my mother died from polycystic kidney disease. Up until that time, I didn't realize that polycystic kidney disease even passed through to the male side of the family. Education about the genetic effects of polycystic kidney disease just simply wasn't discussed, and it wasn't an issue that anybody knew much about.

The interesting thing that I am representing is that a number of families who have this disease as a part of their family history. I believe that it is somewhere between 1 in 500 individuals in the United States, which is just on the kidneys at autopsy, to 1 in 1,000. So there is a high incidence of cystic kidney disease that needs to be looked into.

About a year ago, when my brother discovered that he had some liver problems—he is a medical doctor—we began to have more discussion about that. It was at that time that I began to find out more about polycystic kidney disease myself. That is actually to research it myself somewhat in a scientific direction, and learned that there was a Polycystic Kidney Research Foundation, which had begun just 4 years ago in Kansas City, MO. That particular foundation has been instrumental in these last few years in beginning to get some insight into the disease.

I am here supporting NIH and NIDDK, the National Institute of Diabetes, Digestive and Kidney Disorders. I am here on behalf of funding for that institute.

I would also like to indicate that the foundation itself came into being after an individual, as in my own case, who had polycystic kidney disease. The spouse of the man who started the foundation didn't discover that she had polycystic kidney disease until she was 50 years old. On discovering that she had it, and in her own treatment, she then discovered from her mother's death certificate that her mother had died of polycystic kidney disease, but it hadn't been discussed.

So it is really a hidden disease in the sense that up until recently there wasn't much hope that there was much that you could do about it, so the medical community wasn't spending much time on it.

This foundation, which Dr. Bruning started, they got together with the University of Kansas, and said: What can we do about it? They made a list of things that might work, and he jumped on the idea of this sponsorship of basic research into what needs to be done.

So the promotion of the foundation is simply to have public awareness and research into this issue. For 4 years, now, they have done quite a bit. As I said, I have only learned about it in the last year, but the neat thing that happened initially was that they got the medical community, from an international scope, together to talk about just where are we.

I would like in this situation to somewhat go into my background. When I graduated to Yale, and began to pick my Ph.D. area, astronomy had so many problems out there that it was a nice subject to choose, because there were so many things that you could do.

Similarly, as we began to investigate a couple of years ago what might be done on behalf of polycystic kidney disease, there were many different avenues that you could take, basically, to find out more information for patients. The foundation has done that.

They have set up small research grants directly with private funding. One of those, I would indicate, is in Oregon, at the Oregon Health Sciences Institution. Dr. Bill Danick is working on how you treat infections in the cyst that you get on your kidneys, and the antibiotics that would cross over and become a part of the solution to that problem.

The scientific advisors who are a part of the Polycystic Kidney Research Foundation meet regularly. They try to find out where we are, and chose paths that it makes sense to take.

Let me take a few minutes to talk about the disease itself. It is an inherited disease that occurs at conception, and there is a 50–50 chance that you can develop polycystic kidney disease. As I said, you don't even know that you even have it at this point. There is not a way to find out until you are in your late twenties as a general rule. Yet, by the time you get to be 40 to 50, the cysts on your kidneys have grown to the point that they begin to incapacitate you in the sense of a renal shutdown. It can shut down life itself.

If was a real problem a few years ago. When my grandfather died, they said that he died of stomach ulcers. He obviously didn't die of stomach ulcers, he died of polycystic kidney disease, but it really wasn't understood.

When I checked back 15 years ago at my mother's death, she had cysts on the kidneys that were about the size of a grapefruit. They just grow abnormally. The little nefrons that are supposed to clean the blood develop a problem, and we don't know how, and that is the reason for the basic research. We need to know just exactly how it is genetically coated to cause this to happen, so that we can intervene in the process and prohibit the onset of the disease later in life.

So the cysts fill up with fluid. There is another nasty little byproduct that can hit you, and that is aneurisms that also can be created in some strategic blood vessels like in your cranium or your abdominal area, and they can just burst, and that will be the end of life. That is about 15 percent of the incidents. You live with the risk that if you get under too much stress, it causes an aneurism to burst, it could happen.

I have indicated that it has been discovered, at least studied, and we know that 1 in 500 and 1 in 1,000 individuals in the United States has that, that is quite a few, 450,000 people, a little bit less than Portland, OR, Kansas City, large cities full of these individuas. So every member of this committee has, essentially, constituents who are affected by this.

It is more common than any others that I really wouldn't have guessed a few years ago, and that is, muscular dystrophy, cystic fibrosis, sickle cell anemia, Down syndrome. It is more common than any of those. As I said, it is usually indicated in the third or fourth decade of life. Some of the things that happen to you are: hypertension, which is a natural part of this disease; kidney pain; bladder problems; infections.

These things all happened just out of the blue as you would experience them. I mentioned aneurisms.

The cost, as I understand it, some people of a conservative bent have looked at those, and say that the renal disease costs for the Federal Government for 1987 are about $220 million, that is, the Federal Government will clinically spend to assist patients that amount of money or more. That is an extraordinary cost based on treatment. As I understand it, the total Federal outlay is like $1.3 million in the NIH and NIDDK budget. So the ratio of costs on the clinical side versus the support for research is really out of proportion in my own personal view.

The foundation has been working with the Institutes of Health and NIDDK in the last several years. Thank goodness, they have begun some programs for funding at several universities where they are studying the effects of diet and protein. They are looking at the hypertension issue. They are looking at whether it makes sense to operate on cysts, or not to operate on cysts, and whether you can treat with antibiotics within the cyst.

David is adopted, but my biological son is now 10, and he won't know for another 10 or 15 years whether or not this is something that will impact him. If there is some treatment that can come out of basic research that will essentially offset the onset of this disease, that would be phenomenally helpful.

I am here to urge your support for basic research in this area. After listening to the testimony of others around the table, I know that it is not the only request you have. I also read the paper and know that there are a lot of pressures on the committee and on the Federal Government to cover the costs. I would just urge that this wedge that we have begun to put in place to solve this problem be pressed further in, and not shut down the $1.3 million that is currently going into this at NIH, but as you can, as I can, and as others involved here can, let's increase it.

PREPARED STATEMENT

Senator PROXMIRE. Thank you. We will insert your prepared statement in the record at this point.

[The statement follows:]

STATEMENT OF GERARD F. MOSELEY

INTRODUCTION

Good morning Mr. Chairman, members of the subcommittee and other guests.

My name is Gerard Moseley. I am an educator—actually I am a physicist/astronomer and senior administrator at the University of Oregon. I am here however as a representative layperson to ask for and to encourage your support for continued and increased appropriations for basic research into kidney disease. The National Institute of Diabetes, and Digestive and Kidney Disease [NIDDK] currently provides the only significant Federal research support into the causes of a serious and prevalent kidney disorder, polycystic kidney disease

As a layman, as an individual who has this specific disease, and as an interested representative of many whose family histories have been troubled by polycystic kidney disease, I have been working with the Polycystic Kidney Research Foundation [PKRF] headquartered in Kansas City, MO. My own mother, brother, sister, two aunts, and many cousins have it: perhaps my son will also have it. During the last 3 years the Polycystic Kidney Research Foundation and NIDDK have been working together to promote research and awareness of polycystic kidney disease.

HISTORY AND PURPOSE OF THE FOUNDATION

The PKR Foundation was founded in 1982 by Joseph H. Bruening, a retired Kansas City realtor. Mr. Bruening's family has been victimized by this hereditary disease which, although little-known, affects about 400,000 U.S. citizens. The central goal of the foundation is to promote both public awareness of the disease and research into the cause and cure of the illness.

In 4 short years, the PKF Foundation has expanded its efforts to include regular correspondence to an international list of 1,600 patients, families, friends, and health professionals. The foundation has recently begun to support small specialized research grant projects approved by the foundation's scientific advisors—individuals who have been selected to represent, collectively, the most advanced national research technologies dedicated to the cause and cure of polycystic kidney disease. A genetic roster is also being developed jointly by the foundation and Indiana University School of Medicine to identify inherited disease traits to assist in the research efforts.

A milestone in foundation history was PKRF's sponsorship of the First International Workshop on Problems in Diagnosis and Management of Polycystic Kidney Disease in September 1984. Twenty-five medical researchers from the United States and Europe gathered in Kansas City to report on recent developments in the treatment of the disease. Such a specialized gathering had never occurred. Plans are currently underway to conduct the second such meeting later in this decade.

CURRENT UNDERSTANDING

In order to understand why research efforts around polycystic kidney disease should not only continue but be expanded, it is necessary to know more about this cruel problem. Polycystic kidney disease is inherited and progressive—cysts or fluid filled cavities form in the kidney and liver, and aneurysms form in strategic blood vessels. The most common form is referred to as autosomal dominant, or adult onset polycystic kidney disease [ADPKD] and this variety afflicts 1 in every 500 to 1,000 persons in the U.S. today. To further underscore the incidence of this disease: if all PKD patients were put in one place, they would equal the population of a large city like Kansas City, MO, or Portland, OR; that is, the number would total slightly less than 500,000 people. The disease is more common than several more highly publicized hereditary illnesses—more common than diseases like muscular dystrophy, hemophilia, cystic fibrosis, sickle cell anemian, and Down's syndrome.

Adult PKD is usually diagnosed in a person's third or fourth decade of life, after most have had children. Symptoms may include high blood pressure, severe kidney pain, bladder and kidney infections, and hematuria. The rupture of a cranial or abdominal aneurysm can lead to sudden death of a seemingly healthy individual. The kidneys can grow as large as a football and increase their weight by several pounds. One of my own kidney cysts is the size of a grapefruit. The most feared complication is kidney failure, which usually occurs 10 to 15 years after the first clinical symptoms. This relentless progression to end-state-renal-disease accounts for 8,000 dialysis patients in the United States today.

Based on current cost projections, as much as $220 million could be spent just on end-state-renal-disease treatment for PKD patients in 1987. Given the extraordinary cost outlays associated with life saving techniques after the onset of such renal dysfunction, it is clearly essential that NIDDK continue it's initial efforts to support polycystic kidney disease research. To date, NIDDK has provided the only major Federal resources for this vital research, and even then current research is valued at a relatively modest $1.3 million annually. I would add here that these few funds are terribly crucial and simply cannot be sacrificed in light of the larger problem and total Federal expense required to maintain end-state-renal-disease patients.

REVIEW OF CURRENTLY FUNDED RESEARCH

The PKR Foundation and NIDDK began their important collaboration 3 years ago. In December 1983, the then NIADDK embarked on an expanded research effort with the funding of a 3-year research program project grant involving four universities: the University of New Mexico, University of Kansas, Indiana University, and Northwestern University.

Apart from the Federal resources committed to this project, the PKR Foundation is funding a multiyear companion study at the Oregon Health Sciences University. The foundation has also made possible Project Team meetings at selected locations around the country. In 1985, NIDDK funded a second multiyear study through the University of Colorado Health Sciences Center.

The NIH Kidney Director, Dr. Gary Striker, is an important advocate for continuation of polycystic kidney research. Last year NIDDK also issued requests for proposals to study the pathogenesis of polycystic kidney disease. Several qualified studies were submitted. Regrettably, only one award is expected to be made within the funds currently projected.

CONCLUSION

In conclusion, it is very important that the momentum gained in the last 2 years continue, and as soon as possible be accelerated. The PKR Foundation firmly joins in with the NIDDK in supporting these research investigations, inquiries which ultimately will provide us not just clues but real longer term solutions to this genetic affliction. On behalf of the 1 in every 500 Americans like myself, the PKR Foundation, therefore, strongly endorses continuation of the NIDDK research appropriation.

Again, I personally wish to thank you for this opportunity to speak before you about this important medical condition and the work of the PKR Foundation. Once again I encourage your continued support of the National Institute of Diabetes, Digestive and Kidney Diseases.

Senator PROXMIRE. Dr. Moseley, thank you very, very much. You have done a superlative job. You are a very good argument for having more astronomers in medicine.

Dr. MOSELEY. Thank you.

Senator PROXMIRE. I would like to say just one other thing before I yield to Chairman Hatfield.

You told us that NIH is currently spending $1.3 million on polycystic kidney disease. How would NIH spend next year under the President's budget?

Dr. MOSELEY. I am not an expert on the budget, I wish I were. It is my understanding that it will be trimmed, but I don't know how much. I apologize for not having the answer to that.

Senator HATFIELD. Mr. Chairman, I have no questions. I just want to thank you.

Senator PROXMIRE. Thank you very much for a fine presentation.

STATEMENT OF KATHLEEN HARALSON, PRESIDENT, ARTHRITIS HEALTH PROFESSIONS ASSOCIATION, AND ARTHRITIS FOUNDATION

Senator PROXMIRE. Our next witness is Kathleen Haralson, president of the Arthritis Health Professions Association and the Arthritis Foundation.

Ms. HARALSON. Mr. Chairman, and members of the committee: I am president of the Arthritis Health Professions Association, an association of physical and occupational therapists, nurses, health service researchers, medical sociologists, and physicians, all involved in the care of individuals with arthritis. We are a section of the Arthritis Foundation, and I am personally a physical therapy specialist in rheumatology at Washington University in St. Louis.

I am here today on behalf of the Arthritis Foundation. As we clarified, a couple of testimonies ago, at least 1 out of every 7 Americans has arthritis, and the Arthritis Foundation is committed to their welfare, and vitally interested in appropriations for the National Institute of Arthritis, Musculoskeletal and Skin Diseases.

The research and training that it will support will have direct and profound effects on the enormous population of individuals with arthritis.

Last November, each member of this subcommittee voted for the establishment of the new institute. We are grateful for the support and we are grateful for Senator Weicker's comments at that time, when he asserted that Congress had created NIAMS in response to a national need, and the problem caused by arthritis will not disappear unless focused, well-financed research is supported.

The fiscal year 1987 is the first opportunity for Congress to fund the institute, and allocations must be sufficient to establish it as an effective entity.

Previous witnesses have testified that recent research has opened up exciting new possibilities requiring future exploration. However, to pursue them adequate funding for the institute is absolutely essential.

Historically, in spite of this large population, arthritis research has been characterized by a paucity of funding. We have only very superficial understanding of many rheumatic diseases. Although we can treat and ameliorate the symptoms of some of the diseases, we have not found a cure or a cause for many of them.

The Arthritis Foundation endorses a 1987 NIH-wide funding level of $6.1 billion proposed by the ad hoc group for medical research funding. For the National Institute of Arthritis, Musculoskeletal and Skin Diseases itself, we urge Congress to accept the recommendation of the NIMS Coalition. This is a confederation of over 30 voluntary health organizations, professional societies, and consumer groups. We offer, for the record, a statement that is endorsed by these coalition organizations, many of whom have been represented this morning.

The funding that we recommend would allow for, at best, very modest increases in some areas, and it would at least maintain current levels in others. It would fund 24 new investigator initiated research grants, which would be a necessary improvement over the past 2 years.

The recommended appropriations for clinical investigator and physician/scientist awards will help counter the serious errosion in support for training highly skilled researchers. The $9 million proposed for the multipurpose arthritis centers would at least maintain the current number of 14, although that is well down from a previous one time high of 21.

Very importantly, last year, the Arthritis Foundation urged this committee to fund specialized centers of research in three major areas of health concerns: rheumatoid arthritis, osteoarthritis, and osteoporosis. Although the committee encouraged the NIH to explore their development, funds were simply not available. Resources are essential to initiate this targeted multidisciplinary research approach.

Last, in order for the new institute to be fully functioning, it must have adequate research management, and the NIADDK as it currently exists absolutely cannot administer two institutes.

In conclusion, the total funding recommended by the Arthritis Foundation is $151,650,000 million. We urge you to appropriate this sum in order to launch the NIAMS and provide it with the resources necessary to conduct the research to resolve the problems of 38 million Americans with arthritis.

In conclusion, I might mention that in the cab coming over this morning, the cab driver was wearing a copper bracelet. I would like to point out that each year more money is spent on unproven remedies than on research conducted by the NIH. I think that it is important that we redirect the funds that are spent on clinics in Mexico, copper bracelets, and strange diets toward sophisticated research.

Thank you.

Senator PROXMIRE. Thank you, Ms. Harralson, for a very, very impressive and persuasive presentation.

Would your proposed budget allow the Arthritis Institute to undertake any new clinical trials for arthritis?

Ms. HARALSON. Clinical trials?

Senator PROXMIRE. Yes.

Ms. HARALSON. Yes; I believe it would. On next to the last page, there is a budget, but not specifically for clinical trials.

PREPARED STATEMENTS

Senator PROXMIRE. Thank you very, very much for a fine presentation. Your statement will be included in the record at this point along with other statements submitted for the record on appropriations for the National Institute of Arthritis, Muscolosketal and Skin Diseases.

[The statements follow:]

STATEMENT OF KATHLEEN HARALSON

Mr. Chairman and Members of the Committee, my name is Kathleen Haralson. I am President of the Arthritis Health Professions Association, a section of the Arthritis Foundation, and am a Registered Physical Therapist at Washington University School of Medicine, Division of Rheumatology, in St. Louis, Missouri. I appear today on behalf of the Arthritis Foundation, a national voluntary health organization with 71 chapters and divisions throughout the United States.

The interest of the Arthritis Foundation in appropriations for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) derives from its commitment to the more than 38 million Americans who have arthritis. Research and training supported through this newest NIH institute has direct and profound effects on our population with arthritis.

As this Committee knows, NIAMS was created on November 20, 1985, enacted into law as part of the Health Research Extension Act, H.R. 2409. Members of this Subcommittee supported through your votes the establishment of the new research institute. Mr. Chairman, we were delighted by your floor statement on that occasion, in which you said, "Congress determined in H.R. 2409 that top priority focus is to be placed on arthritis. . . ." You said that "Congress created an Arthritis Institute in response to a national need. The problems caused by arthritis will not disappear unless focused, well-financed research is encouraged and supported."

We are grateful for this solid statement of support for NIAMS, as we are for the support of so many of your colleagues. This budget year, FY 1987, marks the first opportunity for Congress to fund the Institute you created last Fall. We are confident you will want to insure that appropriations for the new Institute are adequate to establish it as a fully functioning entity, able to initiate the focused attack on arthritis you intended at the time of its enactment.

Arthritis Research Advances

Many exciting avenues of research are underway in the arthritis field, as NIH witnesses previously have testified. In rheumatoid arthritis, a specific parvovirus, RA-1, is strongly suspected of precipitating immune responses which result in disease. Use of a hybrid animal model, the MRL/1 mouse, has led to the exciting etiologic implication that some cartilage destruction precedes joint inflammation, instead of the other way around, as previously thought. In the area of treatment, a cancer fighting cytotoxic drug, methotrexate, is found to be effective in reducing rheumatoid arthritis.

Systemic lupus erythematosus (SLE) is the subject of intense research efforts, including the use of monoclonal antibodies to better analyze the disease process and identify genetic predisposition to the disease. Intramural scientists have determined that lupus in mice can be controlled or eliminated by the insertion of a specific protective gene.

Osteoarthritis is another area of heavy research concentration, since some 16 million Americans have this form of the disease. It is clear that osteoarthritis is not merely a "wear and tear" ailment of older persons, but involves protein factors which cause abnormal behavior in cartilage cells. Last year, the NIADDK Arthritis Division held a comprehensive workshop on osteoarthritis which will give further direction to promising areas of research.

Because of the paucity of past funding for arthritis research at NIH, understanding of many of the rheumatic diseases is little more than superficial. We are confident that with a concerted attack, many of the answers may be found in the not too distant future. We are able to treat and ameliorate the progression and disability of some of the arthritides but have not yet found a cure for any of them. The Arthritis Foundation believes that funding at the levels and in the areas we recommend will bring profound advances in a range of scientific inquiry relating to arthritis.

Funding Recommendations

The Arthritis Foundation endorses the FY 1987 NIH-wide funding level proposed by the Ad Hoc Group for Medical Research Funding as the minimum necessary to maintain biomedical research momentum in this country. The amount proposed, $6.1 billion, is a conservative recommendation and is only 1.4 percent above current service levels.

For the National Institute of Arthritis and Musculoskeletal and Skin Diseases, we urge Congress to accept the funding recommendations of the NIAMS Coalition, a recently formed confederation of voluntary health organizations, professional societies, and consumer groups concerned with arthritis, bone, and skin disease research. The Arthritis Foundation and the Coalition concur that $151,650,000 is the minimum amount necessary to preserve the research integrity and the organizational stability of the new institute. We offer for the record a statement endorsed by the coalition organizations.

Specifically, we believe the allocation of $100 million for investigator-initiated research grants is a necessary minimum level for FY 1987. This amount, only about 3 percent over current services, would enable NIAMS to fund 24 additional new grants and bring the award rate up to about 34% of approved grants, with a priority score of 170. This is far below the NIH average of the last decade, but would be an improvement over the last few years, nonetheless.

Last year, the Arthritis Foundation urged this committee to fund Specialized Centers of Research (SCORs) in three target areas. This Committee's Report on the FY 1986 appropriation bill for Labor, HHS, and Education (HR 3424) endorsed the SCOR concept applied to the arthritis field and encouraged NIH "to explore the development of this kind of research center program." The Institute has not the resources to divert to such a program, no matter how important and desirable. Therefore, new funding is essential to initiate targeted, multi-disciplinary research through SCORs.

We believe NIAMS is prepared to move quickly to establish SCORs in three of the greatest national health problem areas confronting that institute: rheumatoid arthritis, osteoarthritis, and osteoporosis. Each of these target diseases would be addressed by three SCORS; each would complement, and be complemented by, investigator-initiated research projects. SCORs represent an exciting new approach to accelerate our scientific knowledge in arthritis and bone disease fields, and we are convinced that support from Congress in the amount of $7.65 million for this purpose would be money well spent.

The Arthritis Foundation is deeply concerned by the erosion in support for research training. Unless funding is increased, no new Clinical Investigator or Physician Scientist Awards would be available in FY 1987. Without training for an adequate number of new and established scientists, we will discover within a few years that the cutting edge of biomedical research will have been irretrievably lost, along with this nation's preeminence. We urge appropriations of $7.8 million to strengthen "other research," which supports research careers awards, Clinical Investigator Awards, and Physician Scientist Awards, and $6.13 million (the current services level) for National Research Service Awards.

Multipurpose Arthritis Centers have been inadequately funded over the past few years, despite this Committee's efforts to maintain them at high levels. The number of centers has dwindled from 21 to 14, and their grant awards have been reduced each year due to limitations on available funds. An appropriation of $11.909 million would fully fund the existing centers at current service levels. We urge the Committee to provide at least this amount.

Research management and support -- the administrative expense account -- urgently needs your attention if the new NIAMS is to be a fully functional entity. Already administratively lean in comparison with other NIH research institutes, NIADDK as formerly constituted and currently staffed cannot now support two institutes. 35 intramural and 14 extramural support slots are now assigned to NIAMS. Another 36 positions are necessary for the operation of the new institute, at a cost of $1.5 million above the President's budget.

Conclusion

The total funding recommended by the Arthritis Foundation for NIAMS is $151.65 million, only $18.4 million more that the estimated current services level of $133.25 million. The National Arthritis Advisory Board has indicated to you in its testimony, as a reflection of the Board's professional judgment, a need for $178.4 million in program funds for NIAMS. We concur that a need for that level of funding exists and would produce good science. The amount we urge you to appropriate would modestly launch NIAMS on its important mission, and it is a level that should be supportable by every member of Congress.

Thank you for the privilege and opportunity to present testimony on behalf of the Arthritis Foundation. I will be pleased to respond to any questions the Committee may have.

STATEMENT OF ROBY C. THOMPSON, M.D., PRESIDENT, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

Mr. Chairman and members of the Committee, I am Roby C. Thompson, M.D., Chairman of the Departments of Orthopaedics and Physical Medicine and Rehabilitation at the University of Minnesota and President of the American Academy of Orthopaedic Surgeons.

I am pleased to appear before you today to present the Academy's position on the need for continued and, if possible, expanded funding of research programs on the musculoskeletal system at the National Institute of Arthritis, Musculoskeletal and Skin Diseases. The Academy is a fellowship organization, with over 12,000 Board certified orthopaedic surgeons. One of its major objectives is to foster, develop and support investigative knowledge of orthopaedic surgery and the prevention of disorders of the musculoskeletal system.

The musculoskeletal system makes up over 70 percent of the body. Its unique tissues are welded into functional units of bones, joints, muscles, tendons, ligaments, nerves, and skin. This system provides for our physical function and our ability to perform the tasks of everyday living.

Musculoskeletal diseases afflict an estimated 32 million Americans and account for over $65 billion in medical expenses and lost earnings each year. These diseases and disorders affect all age groups. For example:

* Osteoarthritis -- the result of wear and tear on joints of the body -- afflicts more than 16 million Americans and markedly diminishes the quality of life.

* Osteoporosis -- loss of bone mass -- affects over half of all women above the age of 45. This condition is considered the leading factor in the 200,000 hip fractures women suffer every year. The costs associated with osteoporosis amount to over $6 billion annually.

* Rheumatoid arthritis is a chronic inflammatory disease affecting both small and large joints, causing pain, immobility, and severe skeletal deformity. The costs associated with arthritis amount to over $8 billion annually.

* Birth defects, spina bifida, scoliosis, and brittle bone disease (osteogenesis imperfecta) are just some examples

of crippling disorders which strike during infancy and childhood.

- Fractures and injuries to the muscles, ligaments, and tendons in otherwise healthy Americans of all ages resulting from accidental falls, motor vehicle accidents, and sports related injuries.

- Low back pain will affect 80% of all individuals during their lifetime. It is the major cause of limited activity under age 45, accounts for one-sixth of all occupational injuries, and is responsible for almost $16 billion in economic costs annually.

- Bone cancer accounts for a small percentage of primary malignancies, but bone is a common and painful site of metastasis when cancer spreads.

The investment of government funds in musculoskeletal diseases research over the past two decades has resulted in substantial payoff to the taxpayers, and more importantly to those individuals afflicted with these diseases. One of the most significant accomplishments has been in the area of destroyed joints from any cause, through the use of artificial implants. Even though the original successful human joint replacements were largely developed in Europe, NIH-sponsored research has resulted in new designs and surgical techniques which have greatly improved the durability and longevity of these implants.

Other major advances in patient care as a result of federal funding for basic research in musculoskeletal research:

- Studies on ligament injuries, their healing response and ways to improve the results of management for patients with these injuries. These studies have improved the results of these joint injuries with better joint motion at an earlier stage and a more stable joint over the long term.

- Improved understanding of the care of the multiply injured patient with earlier stabilization of fractures leading to improved survival and better function.

- Development of new technology to allow management of fractures that shortens hospital stay - decreases complications of injury and allows earlier return to functional status.

Mr. Chairman, basic research is the lifeline of improved patient care. Each new bit of information, added to the existing scientific data base, contributes to the clinical advances and the alleviation of human suffering.

There are a large number of scientific areas that warrant intensive investigation, and the following are but a few of the promising areas:

1. Research on the causes of osteoarthritis, its pathophysiology, and better methods of improving function in the diseased joint to include cartilage grafts and control of cartilage remodeling.

2. Research on joint injuries that often lead to premature arthritis.

3. Research on bone diseases such as osteoporosis, which weakens the skeletal support mechanism to determine the

effects on genetic predisposition, diet, hormones, and environment on the severity and incidence of these diseases.

4. Basic research to develop better design, materials, and fixation techniques for joint replacements and other skeletal implants.

5. Research on the pathophysiology of back pain in order to provide a rational approach to decrease the impact of this major disorder of society.

6. Research on the basic healing mechanisms for bone, ligaments and tendons in order to allow for optimum treatment and rehabilitation following injury or disease.

7. Research on the application of transplants for bone and other connective tissue to determine acceptability, application, and ways of improving their utilization to replace missing segments of the skeleton and its support structures.

Specialized Centers of Research

Mr. Chairman, research in the areas of osteoarthritis, rheumatoid arthritis, and osteoporosis have progressed to the point where a concentrated multidisciplinary research effort should be initiated. A successful mechanism used by many of the NIH Institutes to provide a highly effective means of concentrating research personnel, resources and facilities on diseases of national importance is the "Specialized Centers of Research".

These specialized centers of research provide a valuable compliment to an Institute's portfolio of investigator-initiated research projects. This mechanism provides an institute with the means of stimulating wider research interest in selected high priority areas, and more importantly, these centers insure that adequate support is provided for clinically oriented basic science and its application to clinical problems.

Mr. Chairman, we respectfully urge the Committee to set aside funds at a level of $7.6 million for at least nine specialized centers of research, 3 in each of the major disease areas -- osteoarthritis, rheumatoid arthritis, and osteoporosis. These diseases afflict the fastest growing segment of our population, namely, those individuals over 50 years of age. Unless we take advantage of the research opportunities now before us, the frequency of occurrence and impact of musculoskeletal conditions will become greater in the future.

1987 Budget

The efforts of this Committee to maintain the momentum in science and its attempts to bring hope to those individuals suffering from disease, are severely cut in the 1987 President's budget. While we fully appreciate the difficult fiscal conditions under which you are operating, we believe, like Emerson, that "Health is the first wealth", and thus the government must provide for sound health of its citizens today and into the future. It is with this in mind, that we respectfully urge this Committee to provide $151,650,000 for the National Institute of Arthritis, Musculoskeletal, and Skin Diseases.

Mr. Chairman, I want to thank you and the members of the Committee for the past support of biomedical research and in particular, the research program on musculoskeletal diseases. I will be happy to answer any questions.

STATEMENT OF THE PAGET'S DISEASE FOUNDATION

The Paget's Disease Foundation is pleased to once again have the opportunity to present its statement in support of appropriations for the National Institute of Arthritis and Musculoskeletal and Skin Diseases. As in previous years, we speak on behalf of the estimated three million Americans who are afflicted with Paget's disease of bone, and the health professionals who work to alleviate their distress.

Paget's disease of bone is the nation's number two bone disease, after osteoporosis. Although much less common than the latter, it also affects mainly senior citizens. It is present most frequently in a mild form, and is usually misdiagnosed as arthritis. However, when Paget's disease progresses it can cause devastating pain and crippling. To quote a recent patient who wrote us:

"I have severe Paget's in my spine, i.e. lumbar sacral area, and all across my girdle from hip to hip, but more severe in my left hip. I also have it in both my legs and most severely in my right leg and ankle and knee. My right knee needs a complete replacement operation. I have it in my skull as well, with considerable thickening. My left leg is about an inch shorter than my right and I wear lifts in my shoe with a thicker lift in my left shoe. I have shrunk from 5'10" to 5'7 1/2"... I have to walk with a cane now; my legs are bowed and other than driving a car and short walks, I have no other physical activity... I am 74 now."

Paget's disease has been recognized since 1878, but there has been no cure or help for it until recently. Through research--much of it underwritten by the National Institutes of Health--several drug therapies have been developed which appear to slow down the progress of the disease and alleviate its symptoms.

These drug therapies, however, are far from a panacea. As physicians have worked with them during the past ten years, they have found that numerous patients do not respond to them satisfactorily. Physicians are looking now to more effective forms of the drugs to be developed. At the same time, they are seeking to learn the cause of the disease.

The only current NIH grant for Paget's disease research is to explore the possibility that it may be caused by a slow-acting virus, similar to that causing other diseases such as AIDS. There are very few other researchers working on Paget's disease today, largely, we feel, because the resources for funding grants appear to be highly limited in this area. Also, because the disease has a low-profile in both the public sector and the scientific community, major research focus has been concentrated elsewhere.

The Paget's Disease Foundation was formed nine years ago to help patients and physicians learn about the disease and its new therapies. Because the disease has been so often misdiagnosed or dismissed by physicians, we estimate that only about 200,000 patients are under treatment for their disease.

The Foundation has mounted an on-going public awareness campaign to reach more patients who need help. We are terribly concerned about the paucity of research work being done in Paget's disease and have been meeting with the NIAMS officials to reverse this trend.

As a result, a remarkable event took place last September on the campus of the NIH. About thirty scientists gathered from all over the world to discuss their current investigations relating to bone metabolism and Paget's disease. Among them were top representatives of the fields of endocrinology, virology, cell biology, and angiogenesis. It is unusual for such a diverse group to sit down together to discuss one disease. Their challenge was to pool their knowledge to discover new approaches to understanding Paget's disease of bone.

The two-day meeting developed into an exciting exchange of ideas and information. Each specialist had possible solutions for problems with which another was wrestling. A summary of the meeting will be published shortly. We are anticipating a new spark in Paget's research as a result of the stimulus generated by these researchers.

The meeting itself was made possible by the co-sponsorship of the NIAMS and the Foundation. We have worked as partners together in the past, developing and disseminating educational materials, and we look to future collaborations. Our symbiotic relationship is echoed by similar partnerships between the NIH and constituent volunteer organizations. We non-profits can provide important outreach to the general public, but we cannot bear the burden of research alone--especially such a small organization as ours. This year we are offering our first research grant in Paget's disease of $10,000, as a supplementary incentive to someone already working in the field.

The work of the NIAMS is vital to us, and we urge that Congress appropriate adequate funding for the Institute to maintain its on-going programs. We have joined the Coalition of Organizations Concerned with Programs of the NIAMS to urge that $151,650 be designated for the FY 1987 budget. Any amount less would be disastrous to those in the field who are already operating under crisis conditions.

The Foundation is especially concerned that researchers are distracted from their work by the prevailing atmosphere of cut-backs that has existed during the past few years. The task of applying for Federal funds is arduous, and it is exacerbated by the possibility of already approved support being withdrawn by administrative fiat. A ten percent reduction has the effect of a thirty or forty percent cut-back on productivity in this climate of instability.

Congress has in the past made possible remarkable advances in biomedical research through its support of the NIH. Now is not the time to stop the momentum which will benefit generations to come. Bright young physicians are being given the signal to abandon the path of clinical research. Let us instead give them the green light of support they need to make the breakthroughs we see so very close at hand.

STATEMENT OF THE ENDOCRINE SOCIETY

Mr. Chairman and Members of the Committee, I am Dr. Claude J. Migeon, Professor of Pediatrics, Johns Hopkins University School of Medicine and Director of the Pediatric Endocrine Clinic at the Johns Hopkins Hospital. I represent the Endocrine Society, an association of over 4,000 members who are interested in the study of hormones and in the treatment of hormonal disorders.

Hormonal action in the body is basic to life itself. Because hormones play a major role in the control of many biologic functions, disorders of their secretion have an enormous impact on health and medical costs. It is well known that hormones play a major role in reproduction. During fetal life, they control sexual differentiation; at adolescence, they bring about sexual maturation; during pregnancy, they are necessary for the maintenance of the fetus. Growth hormone and thyroid hormones permit normal development from infancy to adulthood. Parathyroid hormone and Vitamin D control bone and mineral metabolism. Adrenal hormones influence salt and water equilibrium which in turn influence blood pressure. Hormones of the pancreas regulate sugar metabolism and also lipid metabolism. Recent progress in Neuroendocrinology have shown that hormones are involved in behavior and brain function.

Disorders of the endocrine system have a great impact on health and as a consequence on medical costs. They result in abnormalities of sexual differentiation in infants and adolescents, in infertility and multiple sexual dysfunction. Decreased or increased thyroid function are frequent problems. Diabetes and its complications are most troublesome. Osteoporosis resulting in bone fractures takes an awsome toll on aging subjects. It must be noted that hormonal abnormalities are involved in atherosclerosis, hypertension, certain cancers and some psychosis. The extent and diversity of endocrine or endocrine-related diseases demonstrate the need for further investigation in this field.

Endocrinologic research is mainly supported by the National Institute of Diabetes and Digestive and Kidney Diseases and the Reproduction Branch of the National Institute of Child Health and Human Development. It is also supported to variable degrees by all the other Institutes. This permits us to be less parochial than other areas of research and to support the overall efforts of NIH.

Recommendations

1/ Biomedical Research Funding at NIH

We recommend a total budget of $6.079 billion for FY 1987. This would provide for current services plus a modest 1.4% increase for special programs or initiatives.

In many Institutes the rate of grant awards made in relation to the total number of research projects which have been approved has fallen below 25 percent. It is clear that a great deal of biomedical advances are being lost because 75 percent of the projects approved are not funded.

We recommend that adequate funds be provided for the funding of at least one third of all approved new and competitive RO1 Grants. This would include $504 millions for NIDKK.

2/ Research Training

We recommend that special attention be given to the importance of training the investigators of the future. Training continues to be the best long term investment we can make. It may be too obvious, but the spigot of researchers cannot be easily turned on and off. Five to seven years of hard work and education is critical. If we continue to send mixed signals, we will only discourage, if not eliminate this resource.

3/ Equipment and Instrumentation

This is one of the most costly yet most critical parts of research. The technology explosion centers right on research. Many types of new equipment make a great deal of research possible. Just as importantly proper equipment can dramatically speed-up the research we are doing.

We would urge you to continue the past initiatives in funding this area.

4/ Construction and Renovation

Construction and renovation is a scary topic simply because of the need which is estimated at $2 to 4 billion. Some points are evident, however:

- Many of our facilities which were built in the 1950's and 1960's are slowing down our research progress as much as not having the equipment or trainees.
- We would recommend a program of $200 million in fiscal 1987 to get the process started. We would also recommend that there be an equal match of Federal to private dollars as a requirement

for any project to prove the intent and need of those applying. This formula would then mean that the $200 million federal investment would equate to $400 million not to mention the tremendous numbers of both short and long term jobs created.

5/ Flexibility at the NIH

Recent directives and actions by the NIH, the Secretary and OMB seriously impinged upon the ability of the individual institutes to manage their own programs.

Congress has established Advisory Councils at the various Institutes to ensure a wide spectrum of scientific knowledge and input which in turn, has led to the development of priorities.

We strongly suggest that flexibility and some degree of decision-making remain in the various Institutes and their Councils. In particular, we would urge you to adopt bill language restoring this flexibility to the individual Institutes. Report language will not work. Very strong language was used last year and OMB, and the Secretary's office completely ignored it.

IN SUMMARY:

We urge you to continue a strong medical research program and not fall to the whims of short term budget problems. At a time when in 15 months, we are spending more on Defense Research and Development than we have spent in our history on medical research, $6.1 billion for medical research is not at all out of line. Today, we are spending less on medical research as a percentage of health care costs than we were in 1977. If we are ever to reach our goals to prevent and cure diseases, we must develop education, prevention and effective treatment programs. The only way to do that is through medical research.

STATEMENT OF THE COALITION OF ORGANIZATIONS CONCERNED WITH THE PROGRAMS OF THE NATIONAL INSTITUTE OF ARTHRITIS AND MUSCOLOSKELETAL AND SKIN DISEASES

Introduction

The Coalition of Organizations Concerned with the Programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is pleased to have this opportunity to submit its joint statement on FY 1987 appropriations for the newest NIH research institute. The 30 organizations supporting this statement want to insure that the new NIH Institute is properly established as a fully functioning research institute at the earliest possible time.

The members of this Subcommittee are aware that NIAMS was established in law on November 20, 1985. Fiscal Year 1987 marks the first opportunity for Congress to address research needs of the programs encompassed by this new Institute as a separate budget line item.

The President has supported the creation of NIAMS, and the Congress has endorsed it through several nearly unanimous votes. We now urge you to appropriate funds for the new Institute at a level adequate to allow it to initiate the focussed, national research program contemplated by Congress at the time of its establishment.

Research Needs

Arthritis, rheumatic, and related musculoskeletal and connective tissue diseases, comprise over 100 distinct forms, affecting more than 38 million Americans, including as many as 250,000 children. The better known of these conditions are osteoarthritis, rheumatoid arthritis, gout, scleroderma, lupus erythematosus (SLE, or lupus), and ankylosing spondylitis, or spinal arthritis. Many millions more of our people have osteoporosis, osteogenesis imperfecta, Paget's disease of bone, pemphigus, ichthyosis, neurofibromatosis, tuberous sclerosis, alopecia areata, psoriasis, epidermolysis bullosa, Marfan's syndrome, vitiligo, melanoma, skin cancer, and other diseases of the bone and skin. In addition, there are many healthy Americans whose musculoskeletal systems are disabled by falls, fractures, motor vehicle accidents, and sports-related injuries.

All these serious diseases or conditions result in morbidity, mortality, and disability, which cost the American economy many billions of dollars each year in medical care, lost wages and productivity, lost taxes, increased disability and workers compensation payments, and increased social services costs. Research advances in the past decade have brought about improved treatment, control of disease, better diagnostic methods, and important new surgical procedures which strongly indicate that accelerated and targeted research efforts can sharply ameliorate, control, prevent, and cure a number of these diseases. This promise was a major reason for the creation of the new Institute. Now Congress and the President must give our Nation's scientists the means by which to fulfill the promise.

Biomedical research, and more specifically research to improve the lives of as many as 50 million Americans with arthritis, bone, and skin diseases, should be one of the highest of this Nation's priorities. The loss of momentum in biomedical research through reduced or level funding would mean a serious loss of research opportunity for many years to come and the real potential exists for the loss of an entire generation of investigators.

Funding Recommendations

Attached to this statement is a table showing funding necessary to maintain research efforts at current services levels, and the Coalition's recommendations for NIAMS appropriations for FY 1987.

The recommended support level for investigator-initiated research grants (RO-1) would fund 223 new grants in FY 1987, and a total of 612 new and continuation grants. At this level, the estimated award rate for new grants would be 34%, with a priority score payline of 170. The $100 million we urge is only 3% greater than the current services level.

Although the Coalition recommends funding at current service levels for training and contracts, we urge initial funding of Specialized Centers of Research (SCORs) to target multidisciplinary research approaches in three areas: osteoporosis, osteoarthritis, and rheumatoid arthritis, as both House and Senate Appropriations Committees recommended last year. We also request an increase of $2.4 million over current services in Centers funding to support six core centers in dermatology.

The "other research" category includes Clinical Investigator and Physician Scientist awards, both of which must have reasonable funding if our research community is to remain viable in future years. No new awards would be possible under the President's FY 1987 budget. Intramural research must be strengthened to complement extramural activity.

Institute Staffing

At current personnel levels, NIAMS cannot function as an independent Institute. Under the NIH organization plan, the Arthritis and Rheumatism Branch and Laboratory of Physical Chemistry in the NIADDK intramural program are transferred to NIAMS (35 positions), along with 14 extramural personnel. When the administrative separation from NIADDK takes place, an additional 8 slots are scheduled to be assigned to NIAMS. In order to be minimally effective as a working Institute, NIAMS requires another 36 personnel. Under the President's FY 1987 budget, $1 million additional is provided (but no positions) in the RMS (research management and support) activity. If positions are made available, this additional amount will permit the placement of 15 to 20 staff. Another $1.5 million is necessary to provide the minimum of 36 additional personnel.

Conclusion

The Coalition believes that the amounts it is recommending for FY 1987 are fiscally sound and minimally adequate to make NIAMS operational and effective as an NIH research institute. There is substantial scientific justification for the higher FY 1987 budget proposed by the National Arthritis Advisory Board. If the Congress determines these levels to be attainable this year, the Coalition would most certainly support them. At a minimum, however, we urge Congress to enact, and the President to approve, appropriations for FY 1987 at the level the Coalition recommends, to firmly establish NIAMS and to begin the level of research effort essential to finding the answers to the diseases addressed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

LIST OF ORGANIZATIONS
ENDORSING STATEMENT ON FY 1987 APPROPRIATIONS

Coalition of Organizations Concerned with the Programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases

American Academy of Dermatology
American Academy of Orthopaedic Surgeons
American Academy of Physical Medicine and Rehabilitation
American Brittle Bone Society
American Congress of Rehabilitation Medicine
American Lupus Society
American Juvenile Arthritis Organization
American Rheumatism Association
American Society for Bone and Mineral Research
Arthritis Foundation
Arthritis Health Professions Association
Dystrophic Epidermolysis Bullosa Research Association
Federation of American Societies for Experimental Biology
Helen Hayes Hospital
Lupus Foundation of America
National Alopecia Areata Foundation
National Foundation for Ectodermal Dysplasias
National Ichthyosis Foundation
National Marfan's Foundation
National Osteoporosis Foundation
National Psoriasis Foundation, Inc.
Orthopedic Research Society
Osteogenesis Imperfecta Foundation, Inc.
Rehabilitation Institute of Chicago
Society for Investigative Dermatology
Terri Gotthelf Lupus Research Foundation
The Dermatology Foundation
The National Neurofibromatosis Foundation, Inc.
The National Tuberous Sclerosis Foundation
The Paget's Disease Foundation, Inc.
United Scleroderma Foundation

NIAMS

(Dollars in thousands)

	1985 Actual		1986 Appropriation plus Carryover		1987 President's Budget		Current Services		1987 Coalition Proposal
Grants	190/565	$77,554	199/582	$83,599	148/537	$75,011	199/588	$96,712	$100,000
Centers	14	10,064	14	10,231	14	9,317	14	11,909	14,309
Other	67	4,814	63	5,087	56	4,868	63	5,087	7,800
Training	233	6,130	268	6,130	257	5,867	268	6,130	6,130
Contracts	7	2,013	7	2,848	6	2,536	7	3,018	3,018
Intramural Res.	49	6,478	49	6,467	48	6,181	49	7,141	8,000
RMS		1,755		2,136		2,953		3,243	4,743
									7,650*
Totals		108,808		116,498		106,733		133,240	151,650

*New Item - Specialized Centers of Research (SCORs).

STATEMENT OF DOMENIC R. RUSCIO, EXECUTIVE DIRECTOR, COALITION FOR ARTHRITIS AND MUSCULOSKELETAL DISEASES

My name is Domenic Ruscio and I am the Executive Director of the Coalition for Arthritis and Musculoskeletal Diseases.

If I may, Mr. Chairman, I would like to begin by thanking you and your distinguished colleagues for affording us the opportunity to submit this testimony. More importantly, our Coalition wishes to extend its appreciation for all that you have done to advance research in this and other important areas.

As I am sure you are aware, Mr. Chairman, arthritis and diseases of the skeletal support structure are among the most common causes of pain, disability, and disfigurement. Apart from the toll they exact in human suffering, it has been documented that the economic impact of these disorders exceeds $65 billion annually, when measured in terms of the added costs of medical care and lost productivity.

Mr. Chairman, approximately 31 million Americans suffer from arthritis, a disease that encompasses more than 100 different disorders of the joints and connective tissues, including osteoarthritis, rheumatoid arthritis, systemic lupus erythematosus, gout, and ankylosing spondylitis, or what is commonly known as spinal arthritis. Additionally, more than 40 million people are affected by bone and joint disorders, fractures, and injuries of the tendons and ligaments.

Congress recognized the severity and magnitude of these diseases when it created a separate National Institute on Arthritis, Musculoskeletal and Skin Diseases. This new institute, with the help of this subcommittee, at long last will provide an opportunity for a highly focused research program. For although much has been learned about these diseases and disorders, medical science has yet to discover a cure.

Research Needs

Mr. Chairman, rheumatoid arthritis remains the major crippling disorder among the rheumatic diseases. The findings from research over the past few years seem to indicate that rheumatoid arthritis is caused not solely by a single microorganism or a deranged host factor, but rather by different agents generating immune responses that later lead to chronic inflammation in those with genetically determined abnormal immune regulation and biochemical abnormalities.

Many new basic research methodologies have been developed and are now available for finite experiments to test this and other hypotheses. These new technologies include monoclonal antibodies, recombinant DNA, and molecular biology. In addition, new experimental animal models have been developed, such as that induced by immunization with type II collagen.

Mr. Chairman, this search for agents involved in an infectious etiology for arthritis needs to be continued and should include viruses and other latent or slow-acting microorganisms. Because immunological factors play such a major role in causing joint inflammation in rheumatoid arthritis and kidney and blood vessel inflammation in lupus cases, methods need to be developed for selective and specific suppression of those immune responses that mediate such conditions, but do not obliterate the body's defense against infections. The structure, function, and release of the mediators of inflammation, and the processes by which inflammation causes damage to joints and other tissues, must be better understood at the molecular level.

Major advances have also been made in understanding of bone cell regulatory factors, and support for this work, along with initial studies in clinical application of these new developments, should go forward. The continuous remodeling of bone is a complex, multifactorial process. Several controlling proteins recently have been identified and isolated. These new leads should be pursued.

Recommended appropriations for FY 1987

Overall, Mr. Chairman, the level recommended by the President for this newly established Institute is not sufficient to sustain the momemtum of on-going research activities, let alone mount a strong, new attack on these devastating illnesses. While we are mindful of the difficult budget situation Congress faces, we believe that a reordering of the priorities set forth in the President's budget is necessary. With this in mind we recommend a funding level of $151,650,000 for the National Institute of Arthritis, Musculoskeletal and Skin Diseases.

The recommended support level for investigator-initiated research grants (RO-1) would fund 223 new grants in FY 1987, and a total of 612 new and continuation grants. At this level, the estimated award rate for new grants would be 34 percent, with a priority score payline of 170.

Specialized Centers of Research

Mr. Chairman, research in the areas of osteoarthritis, rheumatoid arthritis, and osteoporosis have progressed to the point where a concentrated multidisciplinary research effort is necessary. And certainly one of the most successful mechanisms for carrying out such an effort is the "Specialized Centers of

Research". These specialized centers provide a valuable complement to an Institute's portfolio of investigator-initiated research projects, while providing a means of stimulating wider research interest in selected high priority areas. Perhaps more importantly, these centers insure that adequate support is provided for clinically oriented basic science and its application to clinical problems.

Mr. Chairman, we respectfully urge the Committee to set aside funds in the amount of $7.6 million to support at least nine Specialized Centers of Research, including three centers in each of the major disease areas of osteoarthritis, rheumatoid arthritis, and osteoporosis. These diseases afflict the fastest growing segment of our population, namely, those individuals over 50 years of age and unless we take advantage of the research opportunities now before us, the frequency of occurrence and impact of musculoskeletal conditions will become greater in the future.

Recommended staff levels

It should be noted Mr. Chairman, that at current personnel levels the new Institute cannot function as an independent entity. Under the NIH organization plan, 35 positions in the Arthritis and Rheumatism Branch and Laboratory of Physicial Chemistry in the NIADDK intramural programs are slated for transfer to the new Institute, along with 14 extramural personnel. When the administrative separation from NIADDK takes place, an additional eight slots are scheduled to be assigned to NIAMS.

In order to be minimally effective, the new Institute would require another 36 positions. Under the President's FY 1987 budget, $1 million additional is provided--but with no accompanying positions--in the Research Management and Support activity. If positions are made available this additional amount will permit the placement of 15 to 20 staff. An additional $1.5 million would then be necessary to provide the minimum of 36 additional personnel.

To conclude, Mr. Chairman, fiscal year 1987 marks the first opportunity Congress will have to act on its commitment to focus greater research emphasis on arthritis and musculoskeletal diseases. We urge you to do all you can to provide the new Institute with a solid foundation for the future.

Thank you, Mr. Chairman.

STATEMENT OF ROBERT K. DRESING, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CYSTIC FIBROSIS FOUNDATION

Senator PROXMIRE. The chairman will be back shortly. I will continue as long as I can, but there is a vote going on again on the floor.

Our next witness is Robert K. Dresing, president and chief executive officer of the Cystic Fibrosis Foundation.

Mr. DRESING. Thank you, Senator Proxmire. I appreciate the opportunity to appear again before this committee. We have submitted our testimony for the record, and I would like to take just a couple of minutes to bring you some personal reflections.

First of all, the news is good. When we last appeared before you, we had no idea where this gene for this No. 1 genetic killer of children was placed in the human genon. In the last 6 months, we have not only been able to identify what chromosome it is on, but we have been able to narrow the segment of that chromosome down to a very, very small segment, to the point that we really are within striking distance of having the gene for this disease.

The good news about that is that besides our ability to have the gene, we will be able to know how that gene is expressed at the cellular level, and begin to look at therapies that can intervene with the progress of this disease, that can literally change the course of this disease within the children who have it today.

I am the president of the Cystic Fibrosis Foundation, but much more importantly, I am the parent of a 20-year-old son who has this disease. That in itself is a great accomplishment for us because when Robbie was born and diagnosed at 18 months, we were told that he would probably not survive his early childhood. The mere fact that he is going to be 20 is some indication of our success.

Senator PROXMIRE. Mr. Dresing, I am going to have to interrupt you. You can provide a very, very interesting perspective in view of your position and also your family situation. That is a very impressive combination. I am going to have to run to the floor, and we will have to suspend the hearing for just a very, very few minutes as I understand that Chairman Weicker is on his way back. Unfortunately, I have not missed a vote in 20 years, and I don't want to start now.

Mr. DRESING. I don't want to be the cause of that.

[A brief recess was taken.]

Senator WEICKER [presiding]. The committee will come to order, and Mr. Dresing will continue his testimony.

Mr. DRESING. Thank you very much, Mr. Chairman.

I must take a moment to thank you personally for your efforts on behalf of biomedical research. I heard your charge to the National Health Council luncheon a few weeks ago, where you honored Doris Tolson, who is our past president, and we heard what you said. We are here because of that today.

Senator WEICKER. Thank you very much.

Mr. DRESING. I said, briefly, that the news that we bring is good news. We have basically been able to identify where in the human genon the illusive cystic fibrosis gene is hiding. Six months ago, we had no idea where that was. In fact, we were not even sure of whether it was a single gene defect.

We now have been able to get to the chromosome and to the segment of the chromosome where the gene is, and basically are within striking distance. It is our hope that when we appear before you next year, we will be able to tell you that we have not only found the gene, but we have made significant effort toward being able to control this disease and to change the course of the disease within the children that have it today.

So we are not talking about just eliminating the disease from future generations, but we are talking about being able to impact a large population and giving them a quality of life that is acceptable.

It has been since polio that a disease has been cured, and there are a lot of references to cystic fibrosis being the polio of the 1980's. Our fear is that if we don't continue to pursue every avenue that is available to us today for this disease, we may miss the brass ring, and that would be intolerable.

For us to be satisfied with small cuts, or holding our own at a time when the biomedical research world is exploding with opportunity to really change disease is intolerable. We are a very fragmented industry, if you can call us one, that every one who has heard the tragedy that has been paraded up here today, but the opportunity to change that is now. Not to take advantage of that is unacceptable to us.

We are fragmented, but we are going to do our darnedest to make sure that we pull together so that biomedical research is not a victim of what is happening in budgets today. To think that the disease could take lives in the very near future that may not be the result of the disease, but could be the result of budgetary priorities or Gramm-Rudman is intolerable to us.

You, Mr. Chairman, have provided for the Congress leadership that has pervaded this committee, certainly. We are imploring upon you to make sure that that happens on the floor, and we will do everything in our power to see that it happens.

I am the parent of a son with this disease. The only spokesman that Robbie has is his parents and the foundation which supports him. We are supporting the NIH level of funding at $6.1 billion, which is a minimum to take advantage of the opportunities that are before it.

We have heard a lot about cost effectiveness, and we appreciate that, and we understand it. But last year, society spent $300 million to keep our population alive, and they spent $12 million on research to close the doors on the disease. I don't understand that. My son doesn't understand that. We want and we need the leadership that you have provided over the years to get to the floor at the time that they make that important X on the ballot.

Thank you for what you for us on behalf of my son and the 30,000 kids.

PREPARED STATEMENT

Senator WEICKER. Mr. Dresing, thank you very much. I can assure you that within a matter of hours we will be on the floor of the Senate trying to affect the budget in the positive way that you would like.

Mr. DRESING. We appreciate that.

[The statement follows:]

STATEMENT OF ROBERT K. DRESING

Mr. Chairman and Members of the Subcommittee:

My name is Robert Dresing, and I am president of the Cystic Fibrosis Foundation. I have been involved with the Foundation for nearly 18 years. Most importantly, I am the parent of a son with cystic fibrosis, the most common fatal genetic disease in the United States.

By approaching his twentieth birthday, Rob has already beaten many odds. He has lived substantially longer than most of the children with CF born in the early 1950's, who died before they reached kindergarten.

Rob is part of a new generation of children with cystic fibrosis who have survived long enough to become young adults. Nearly half of the children with CF today will live beyond age twenty-one. To do this, they must undergo rigorous physical and nutritional therapy every day. On top of these efforts, they try to pursue their educational, personal, and career goals.

Young adults like Rob know they are lucky to have survived this long. But we, their parents, face the daily reality that without new treatments or a cure, our children stand to face their twenties fraught with hospitalizations, repeated lung infections and finally death from respiratory complications.

The Cystic Fibrosis Foundation is an organization committed to changing that dread future with new treatments and a cure for this disease. We want to rid our country of CF, just as our children want to rid their lungs and digestive tract of the thick and clogging mucus that interferes with their breathing and digestion.

For our part, we have carefully designed our research program to meet NIH suggestions for encouraging the growth and quality of CF research. We are the first voluntary health organization to have ever launched a research center program that combined private and public funds. We have developed our own research centers, care centers, project grants, clinical trials and special grants. These efforts are not intended to either stand alone or duplicate NIH efforts, but rather to complement them. Many scientists who were initially funded by the Cystic Fibrosis Foundation are now receiving long-term NIH support. We have jointly sponsored conferences and studies with the NIH and have actually given the NIH funds for research.

These complementary efforts have led to rapid research progress. By sharing these exciting advances with you, I wish to underscore the need for keeping NIH funding a top priority and not destroying the groundwork that we have laid to solve CF.

For the first time in the 30 years since the CF Foundation was established, we have made impressive strides towards finding the gene that causes this inherited disease. In the last seven months, researchers have narrowed the search for the CF gene to less than one-tenth of one percent of the body's total DNA and established that this CF gene is located on chromosome 7.

A year ago, when our Foundation testified before you, we had no idea where the CF gene was located. All we knew was that researchers needed to find this gene before they could uncover its abnormalities. Recognizing this need, the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) and the National Heart, Lung, and Blood Institute (NHLBI) jointly sponsored a special request for applications.

The initial search for the CF gene among the body's four to six billion base pairs of DNA was like looking for a needle in a haystack. It meant systematically searching for markers, or tell-tale signs of DNA, that would indicate that the CF gene was nearby. And yet, by last October, two researchers supported by this joint NIDDK/NHLBI funding discovered such a marker, narrowing the search for the CF gene to a mere one percent of the body's entire DNA.

The next step was to find a marker even closer to the CF gene that would narrow the search even further. Here again, the diverse research funding of the NIH played a key role. At the NIH-sponsored Frederick Cancer Research Facility, Dr. George Vande Woude identified a marker on chromosome 7 in a research project unrelated to CF. He sent this marker to Dr. Raymond White at our Cystic Fibrosis Research Center at the University of Utah for additional testing. Dr. White, whose work is supported in part by the National Institute of General Medical Sciences (NIGMS), was able to establish that this marker from the Frederick Cancer Research Facility was within striking distance of the CF gene. His discovery has narrowed the search for the CF gene to one-tenth of one percent of the DNA.

This remarkable sequence of events could not have happened without the adequate and diverse NIH funding that allowed scientists supported by four different institutes to contribute to CF research progress in varied and extremely valuable ways.

The amazing pace of these last several months brings home the fact that cystic fibrosis is a disease that is finally ready to be solved. We have reached a point where the knowledge needed to conquer CF is developing right now. Today, cystic fibrosis is the frontrunner - we're stretching the genetic and cell technologies that will benefit not only our children but those with other diseases. The thirty years of slowly acquiring pieces of knowledge about cystic fibrosis are falling into place at last.

The next steps for CF research are clearer than ever before.

While geneticists move in on the CF gene, other researchers can work on pinpointing how this gene affects the cells. Thanks to other NIH-supported research, we already have a clue -- salt has been found to move abnormally in and out of certain cells. Today, we can use the genetic and the cellular approaches to work from both ends towards conquering CF.

However, at this promising time, future research is being seriously threatened by the President's proposed 1987 budget and certain applications of the Gramm-Rudman law. While we respect the Congress' efforts to control the deficit, we ask that rather than implementing across-the-board cuts, the Congress exempt from Gramm-Rudman cutbacks the health programs so vital to our country's future. The grand opportunities offered by new genetic and cellular science mean we must maintain our priorities in health funding. It would be unfair to halt the very progress that is a result of our conscientiously laying the groundwork to promote the NIH's research possibilities.

Currently, the total NIH commitment to CF-related activities exceeds $12 million, largely allocated to the NIDDK and the NHLBI.

If the President's proposed budget for FY 87 is approved by the Congress, the NIH's noncompeting grants will be reduced by over 11% and new and competing grants by over 16%. The number of competing grants will fall to approximately 5100, with less than 30% of all study-section approved projects expected to be funded, meaning that many projects of high scientific merit would not be awarded.

Further, as the OMB increasingly dictates line item spending, the NIH is no longer able to choose the funding mechanisms most appropriate to the diverse stages and types of medical research. The negative impact of NIH's lack of control over funds can be seen in the limit placed on the number of research centers. Our own experience with eight Foundation-supported research centers is that they foster novel and multi-disciplinary research that cannot be captured in single project awards.

Also seriously threatened by both the cuts and control of funds is the NIH's own intramural program. This fine biomedical research program is a leader not only for this country but for the world.

As scientific knowledge burgeons, our country will need to fill the new void with well-trained scientists. The major cuts proposed for NIGMS training slots could damage our country's ability to meet future medical challenges.

It also appears that neither the NIDDK nor the NHLBI will be able to fund any of their planned clinical trials for FY 87 under the President's proposed budget. Additionally, the proposed cutbacks for General Clinical Research Centers (GRCCs) would limit the settings for clinical research. Without NIH support, many promising therapies that deserve clinical trails will be kept just out of the reach of the people who desperately need them.

As the parent of a child with CF, I strongly believe that I cannot ask others to help my child if I do not do everything in my own power to help him. But we as a Foundation know that our efforts alone cannot conquer this disease. Therefore, we support the recommendations of the Ad Hoc Group for Medical Research Funding. We recommend a funding level of $6.079 billion for the NIH. We emphasize the need for program balance at the NIH with a diversity of support mechanisms. We urge you to assure a high degree of flexibility in the management of the NIH for the best use of those funds. We also ask you to support growth in research career awards, research traineeships, clinical research projects and trials, and research centers.

Mr. Chairman, we finally know the path that future cystic fibrosis research must take. That in itself is a major accomplishment for which I thank you and the members of this Subcommittee. But even though the path is straight ahead, we will need adequate and diverse NIH funding to follow it. We are dependent on your leadership to ensure that the children who have survived this long will have the opportunity to benefit from the new treatments and cure which your thoughtful funding can bring to pass.

STATEMENT OF ANNE PLUMMER ON BEHALF OF PARENT COUNCIL FOR GROWTH NORMALITY

Senator WEICKER. Now, everybody, the bad news is that we are way behind, and unfortunately there are caucuses both for the Republican and the Democratic Parties that are going to start shortly. So I would appreciate it if everybody would please keep to the time limit. I wish I had more time to engage in a back and forth, but we are limited, and that is probably why there will be less questioning, not that your testimony is not valuable because it certainly is.

Anne Plummer, Parent Council for Growth Normality.

Ms. PLUMMER. Good morning, Senator.

My name is Anne Plummer, and I am a member of the Parent Council for Growth Normality, an organization of parents and health professionals who are concerned with the problem of short stature and growth delay.

For the last 20 years, over 10,000 children in this country have received treatment for growth disorders through the efforts of the National Pertuitary Foundation, an agency which was funded under the auspices of the National Institute of Diabetes and Digestive and Kidney Diseases. My daughter Amy is one of those children. With the growth hormone, she grows at the rate of about 2½ inches a year, and without it, she will not grow at all.

In April of last year, the unthinkable happened. It was learned that three young Americans, who had been taking growth hormones in the early 1960's of Creutzfeldt-Jakob disease [CJD], a very rare and fatal neurological disorder.

I have with me today, Mr. and Mrs. Lloyd Tatlock of Texas, who are the parents of one of the young men who died, Wayne Tatlock.

A fourth case was later discovered in England. Because the incubation period may be several decades long, the CJ disease is almost unheard of in those under 30 years of age. Since a known transmission method is through the exposure to contaminated brain tissue, the link to human growth hormone, which is produced from pituitaries, which are harvested from cadavres, was clear.

The medical community was caught by surprise, although there was one person who did have foresight. Nobel Laureat, Dr. Carlton Gadjusek of the NIH had predicted 3 years earlier the possible CJD contamination of human growth hormone supplies, but unfortunately no one listened.

So now we live with the spectre of CJD over our lives. The course of the disease is rapid and devastating. Many have likened it to Alzheimer's disease in fast forward. With the onset of symptoms, there is a progression to erratic behavior, memory loss, difficulty in walking, loss of muscle control, vision disturbances, to total helplessness, and then finally death.

There is presently no treatment or cure, CJD is always fatal. It is essential for the future of our children that a long-term epidemiological study be conducted to identify and gather information on health status of as many growth hormone recipients as possible. Identification of the entire pituitary hormone cohort is necessary in order to determine whether any cases of CJD have gone undetected.

In addition, these individuals must be followed for a period of approximately 10 years due to the long incubation period of the CJD organism. The survey will require the expenditure of $1.6 million initially, and $10 million over the life of the study. This breaks down to approximately $100 per person annually.

Although progress has been made in the initial phases of the study, continued funding is very much dependent on the overall funding levels for NIDDKD in fiscal year 1987.

The Parent Council for Growth Normality is committed to seeking implementation of the epidemiological study by every appropriate means. Only by its implementation will our families be accurately apprised of the risk factors they must confront.

Without the knowledge that the survey will provide, families would be forced to confront an unknown risk as to the next 10 or 15 years. To ask them to bear that burden is intolerable and morally indefensible.

The information to be acquired by the survey is basic in making life decisions and maintaining emotional health.

The inadvertent experiment in the transmission of CJD through HGH supplies has already been conducted. It would be extremely poor science, and a tragic waste of human resources not to analyze what has happened. Losing the opportunity to collect this data could seal the fate of future CJD victims.

Congress has in the past requested support for the study, in report language to the NIDDK accompanying the fiscal year 1986 in the House appropriations bill. I am here to ask you for continued expression of this support essential to the research into HGH and CJD is the funding of the NIDDK at the current level of $504 million.

PREPARED STATEMENT

It is said that our children are our future. It is only through the continued funding of the NIDDKD that our children will have a future to look forward to.

Thank you.

[The statement follows:]

STATEMENT OF DIANE C. COUSSAN, PRESIDENT, PARENT COUNCIL FOR GROWTH NORMALITY

I am Mrs. Diane C. Coussan, mother of a growth hormone deficient child, and president of the Parent Council for Growth Normality, a nationwide organization of families whose children require therapy with human growth hormone (hGH) for normal physical development. In the limited space and time provided, it is my intention to report on the crisis in the treatment of children with growth hormone deficiencies, the status of efforts to deal with this situation, and the necessity of seeking solutions within the context of appropriations to the National Institutes of Health.

In April of 1985, my family, along with approximately 12,000 others, was devastated by the suspension from distribution of pituitary-derived hGH following the deaths of three young men who had received hormone supplies produced and distributed by the National Hormone and Pituitary Program (NHPP), an agency funded under the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD). The deaths were linked to contamination of a still-undetermined number of hormone lots by Creutzfeldt-Jakob disease (CJd), a rare, degenerative, neurologic disorder for which there is no known treatment or cure.

In compliance with FDA requests, two commercial producers of pituitary hGH withdrew their products shortly thereafter, leaving all our children with no safe source of the treatment they desperately needed, and facing the specter of exposure to an incurable disease.

The impact of these events was heightened by the fact that most families, including my own, found that there was no coordination or agreement in information released to and by physicians, the FDA, or other official sources **because of the serious lack of data** on this disease in these circumstances.

As information gradually became available, the truly horrifying nature of our predicament became apparent. In seeking a more normal and fulfilling life for our children, by allowing treatment with a product represented as being safe, standard medical practice, we had unwittingly exposed them to a disease whose symptoms have been described as "Alzheimer's in fast-forward." With the onset of symptoms, there is a radid progression through erratic behavior, memory loss, difficulty in walking, loss of muscle control, and vision disturbances, to total helplessness and death, usually within a year.

To add to the nightmare nature of this disease, there is no diagnostic test for CJd, no method to indicate exposure or infection, until these symptoms occur. Often called a "slow virus," CJd can take up to twenty years to manifest itself after infection. There is presently no treatment or cure; CJd is always fatal. At this point, scientists lack sufficient data to say what amount of CJd slow virus, or over what period of time, would be required for the disease to develop in our children.

With the onset of the crisis, FDA and NIDDKD officials determined that two steps were necessary in assessing the nature of the risk to our children: inoculation of animals with as many lots of NHPP hormone as were available, and an epidemiological survey to identify and gather information on the health status of as many recipients of the hormone as possible. It is only through these methods that officials can 1)try to pinpoint infected hormone lots, and 2) determine how many other recipients may already have died from CJd as a result of these NHPP supplies. Compiling and analyzing this data is the only way to give an estimate of the risk of CJd death to the remaining hGH recipients.

Although the animal study is underway, the critical epidemiological survey remains in limbo. Epidemiology of this type is a basic prerequisite to the study of any disease. The extreme rarity of CJd in a young-adult population (and therefore the liklihood that it may be misdiagnosed), its long incubation period, the fact that NHPP pituitary hormone use stretches back over twenty years, and the lack of medical knowledge of the effects of low-dosage exposure over a period of years, all point up the necessity for this survey.

The survey, as proposed, will gather data on as many recipients of NHPP hormone as possible, to determine if there are any other, unreported cases of CJd in this group. Deceased patients will be cross-checked for cause of death. All living recipients will be followed over a period of several years to track any future CJd cases.

Despite scientific concensus on the necessity of this study, expressions of concern from Congress, and the passage of over a year since the crisis began, contracts required for project implementation, as well as funding commitments, have yet to be approved. To date, only "Phase I" questionnaires have been sent to physicians. These were funded by money diverted from the suspended NHPP hormone distribution program, and required no external contracts. The physician surveys, although necessary to the body of data, were described by the Quarterly Report of the Public Health Service Interagency Coordinating Committee on CJd/hGH (September, 1985), as "...inadequate, by themselves, to ascertain all cases of CJd because the incubation period is so long that many patients will no longer be followed by their pediatricians during the time when CJd is likely to occur." (The three victims were in their twenties and early thirties.) The enormity of the task of locating recipients is compounded by the lack of methods to readily identify substantial numbers of patients from NHPP records.

Of further concern to our families is the present exclusion of commercially-supplied hormone recipients from the proposed survey. Although there have, as yet, been no deaths in this group, the long incubation period makes it unlikely that CJd has had sufficient time to manifest itself, if these supplies, with similar sterilization problems in terms of this disease, were also contaminated. It must be remembered that FDA concern was high enough to request the withdrawal of these products from the market, they have not been reinstated, yet their safety has yet to be addressed in terms of CJd risk.

By any reasonable standards, an inordinate period of time has passed without the implementation of the basic studies necessary to define the nature and extent of the risk to which our children have been exposed.

The longer full implementation is delayed, the greater the monetary and manpower costs become. FDA officials have confirmed that the three deaths which have already occurred could easily have been missed. Identification of recipients, particularly NHPP recipients going back to 1963, becomes steadily more difficult as time passes.

The "experiment"--inadvertent CJd transmission through hGH supplies--has already taken place. It would be extremely poor science, and a tragic waste of monetary and human resources, not to collect the data it provides. Epidemiological data forms the basis of such medical research. The medical-scientific community has stressed the unique opportunity to study an identifiable group exposed to a particular neurologic disorder, and the potential value of this research. Losing the opportunity to collect this data could seal the fates of future CJd victims, the majority of whom are not yet within the time frame for CJd symptoms to appear.

In calling for the immediate implementation of the epidemiological survey, we, as parents, look not only at what has already happened, but also to the future. We are aware that three years ago Dr. Carlton Gadjusek, Nobel Laureate and foremost authority on CJd, warned of the potential problem with hGH contamination. Had such a study been put in place then, how much further along might we be? Must we wait for three more years, or three more deaths, before this survey becomes a reality? Without this study we, and our children, can form no realistic estimates of CJd risk in our futures. We must live with the fear of this tragedy for the next twenty years, with no idea of the odds that it may strike our lives. With this study, we can make informed life decisions based on accurate knowledge of our risk, and may well find hope of a healthy future for our families.

The National Institutes of Health, specifically NIDDKD, is the proper agency to conduct this vital epidemiological survey. As the Institute responsible for endocrine disorders, they funded production and distribution of pituitary hGH through the National Hormone and Pituitary Program, which resulted in three deaths due to CJd contamination of those supplies.

It is only within a research structure such as that offered by the National Institutes of Health that the necessary potential for interdisciplinary cooperation and flexibility exists. The crisis facing our families overlaps into concerns involving the Institutes for neurology, child health, and mental health, among others. To their credit, NIDDKD has attempted to stimulate funding commitments among other involved agencies, but has met with little success.

A product produced and distributed under NIDDKD has killed three young men. NIDDKD is in a position to conduct the survey of the risk to 12,000 other young people. While the Parent Council is aware that the NIH appropriations are not line-item, strong report language can go a long way in expressing the will of the Congress and the people. On behalf of all our children, I urge you to express your support.

Senator WEICKER. Thank you very much. Mr. and Mrs. Tatlock, do you have anything that you would like to comment on?

Mr. TATLOCK. We are appreciative of what has been done, and we are very concerned about the parents of children who are receiving these treatments, that they are living with the spectre over their head. As she said, there have only been three or four cases, and no one suspected the CJD at that time, it has only been in the last few months.

So all the research has to be done in order to help the parents with immunization programs, or some type of treatment even if their children do come down with the disease. We are very concerned for them, and we are very, very supportive of their efforts to maintain their equilibrium in this time, and to solicit funds from the Government for the research.

Senator WEICKER. Is there a new growth hormone that has been developed?

Ms. PLUMMER. When the deaths occurred, the growth hormones were withdrawn by the FDA. The children are now being treated with protropine, which is a product of gene splicing, so there is ongoing treatment, but still the question is what the risk was, which has not been answered and will not be answered unless we can collect the epidemiological data.

There is a real problem, and we are going back 20 years or more trying to identify who the recipients of this growth hormones were. In many cases, the CJD remained undiagnosed in life. The Tatlocks themselves, their son was not diagnosed in life as having CJD, it was only confirmed upon autopsy. So we really do need this data in order to be sure of exactly what we are facing.

Senator WEICKER. Thank you very much, and thank you for being part of the hearings.

Ms. PLUMMER. Thank you.

STATEMENT OF MONA SCHLOSSBERG, SECRETARY, INTERSTITIAL CYSTITIS ASSOCIATION

Senator WEICKER. Our next witness is Mona Schlossberg, secretary of the Interstitial Cystitis Association.

Ms. SCHLOSSBERG. Thank you, and good afternoon.

Senator WEICKER. Good afternoon.

Ms. SCHLOSSBERG. My name is Mona Schlossberg. I live in New York, and I have come here today as a representative of the Interstitial Cystitis Association.

Interstitial cystitis [IC] is a disease that very few people have ever heard of, I certainly never heard of it until I had it 3 years ago.

IC is an inflammation of the bladder wall. No one knows the cause, and there is no cure. Chronic inflamation causes scarring which causes the bladder wall to stiffen. This results in decreased bladder capacity, leading to a constant urgent need to urinate.

It is a very painful condition, and although it is not a terminal illness, it has led to suicide and suicide attempts. Symptoms are similar to urinary tract infection, except that it is not caused by bacteria and, therefore, it does not respond to antibiotics. It has been described like a knife in one's bladder, or a lit match in one's pelvis.

Patients are forced to live with chronic, severe, debilitating pain, unrelieved by traditional prescription pain killers.

Most women are unable to have intercourse and, therefore, unable to have children. This leads to many divorces, and in younger women essentially halts any normal social life or prospects of marriage.

Many patients have to urinate as many as 60 to 100 times a day. These patients are literally confined to their homes, cannot travel or function normally in any way. They can't even make it to the local supermarket.

Because of these debilitating problems, patients are frequently unable to keep their jobs.

In addition to the devastating pain of this disease, the typical victim often goes undiagnosed or misdiagnosed. Most people with IC have seen 10 or more doctors, and undergone needless, painful diagnostic procedures and sometimes unnecessary surgery. The average patient may go years before having IC diagnosed.

Very little is known about this disease. Once considered rare, it is now estimated that over 500,000 people in the United States are afflicted with this disease. The ratio of female to male is 10 to 1. There have been no formal studies made in this country on this disease at any time.

There is no cure for interstitial cystitis. There are a few treatments that offer temporary relief to only some patients. Elmiron, which is not approved by the FDA, has been made available through the cooperation of the NIH to urologists who make a special request application to the NIH for this drug.

We are most appreciative of the efforts of the NIH to make this drug available as it was initially very promising. Unfortunately, it has not been that successful, and more research needs to be conducted for better, safer treatment using larger patient population studies.

Other than this small research project that Dr. Parsons at the University of California has been working on, where there is about a 50-patient population study, there has been no other study, federally sponsored or privately sponsored, of this disease.

As an organization, the ICA has done remarkably well in the 2 short years since we have been established. With the help of the media, including the New York Times, the Washington Post, and "Good Morning America," ABC nationwide TV, we have all found each other, established a network across the United States. We have a prestigious advisory board with the best urologists in the country. We have top medical centers interested in doing research, the University of Pennsylvania, Boston University, Tufts Medical College, and the University of California at San Diego.

Although little has been done on IC, we feel that in a relatively short period of time, with funding from the NIH, we can find an answer.

The first national conference on this disease will be held in Boston this September. Without funds, research cannot be continued, and thousands of us will be forced to exist under agonizing conditions day in and day out, without any hope. We will work with you, we will do any work that is necessary.

I would like to read a paragraph written to us by a young woman from California:

> In the past 6 months, my condition has intensified to the point where I am unable to function as a normal human being. Crippled with pain, I have been unable to pass the California bar exam, unable to work and have had to cease all sexual activity with my husband. In the past few weeks, I have been bedridden with pain.

I have had interstitial cystitis for 3 years and live with chronic pain. Unlike many other organizations, our members are all victims of interstitial cystitis, and are sick and unable to fight for research and treatment.

There are many people more debilitated than I from States across the country. With great effort, I made this trip to Washington and I am speaking on behalf of all those homebound, too sick to come, and ask for your help. There is not one drug that can be used effectively to lessen the pain. We have thousands of women today, and men, diagnosed with IC who have nowhere to turn for help.

PREPARED STATEMENT

We appeal to you today to help us find a cure, and initiate research that would provide a drug for safe and long-term relief. Without funds, we have no hope. Please help us.

Thank you.

[The statement follows:]

STATEMENT OF MONA SCHLOSSBERG

My name is Mona Schlossberg. I live in New York and have come here today as a representative of the Interstitial Cystitis Association.

Interstitial Cystitis is a disease that very few people have heard of. I certainly never heard of it, until I unfortunately came down with the disorder three years ago.

I.C. (interstitial cystitis) is an inflammation of the bladder wall. No one knows the cause, and there is no cure. Chronic inflammation causes scarring which causes the bladder wall to stiffen. This results in a decreased bladder capacity leading to a constant, urgent, need to urinate. It is a very PAINFUL condition, and although it is not a terminal illness, it has led to suicide and suicide attempts. Symptoms are similar to a urinary tract infection, except that it is not caused by a bacteria, and therefore does not respond to antibiotics. It has been described like 'a knife in one's bladder, or a lit match in one's pelvis'.

1. Patients are forced to live with chronic, severe, debilitating pain, unrelieved by traditional prescription pain killers.

2. Most women are unable to have intercourse, and therefore unable to have children. This leads to many divorces, and in younger women, essentially halts any normal social life, or prospects of marriage.

3. Many patients have to urinate as many as 60-100 times a day. These patients are literally confined to their

homes, cannot travel, or function normally in any way. They can't even make it to the local supermarket.

4. Because of these debilitating problems, patients are frequently unable to keep their jobs.

5. In addition to the devastating pain of this disease the typical victim often goes undiagnosed or misdiagnosed. Most people with IC have seen 10 or more doctors, and undergone needless, painful diagnostic procedures and sometimes unnecessary surgery. The average patient may go years before having IC diagnosed.

Very little in known about this disease. Once considered rare, it is now estimated that over 500,000 people in the U.S. are afflicted with this disease. The ratio of female to male is 10:1. There have been no formal studies on IC ever conducted in this country.

There is no cure for IC. There are a few treatments that offer temporary relief to only some patients. Elmiron, which is not approved by the FDA, has been made available through the cooperation of the NIH to urologists who make a special request application to the NIH. We are most appreciative of the efforts of the NIH to make this drug available, as initially it was very promising. Unfortunately it has not been that successful. More research needs to be conducted for better, safer treatments using larger patient population studies.

In the past, IC was considered a psychosomatic disorder - one of those female 'hysterical' ailments. This myth was perpetuated in Campbells' Urology, the standard urology text, until recently - August 1985, when the chapter was finally rewritten, and IC was given its proper place as a real disease. We now face the problem, that many urologists have been trained on inaccurate and outdated information. This adds to the problem of early diagnosis.

As an organization, the ICA has done remarkably well in the two short years since we established ourselves. With the help of the media, including the New York Times, Washington Post, and Good Morning America - ABC nationwide TV we have all found each other and established a network across the United States. We have a prestigious medical advisory board, with the best urologists in the country. We have top medical centers interested in doing research - University of Pennsylvania, Boston University, Tuft's Medical Center, University of California at San Diego.

SO LITTLE HAS BEEN DONE ON IC, WE FEEL THAT IN A RELATIVELY SHORT PERIOD OF TIME, WITH FUNDING FROM THE NIH, THAT WE CAN FIND AN ANSWER.

The first national medical conference on this disease will be held in Boston this September. Without funds, research cannot be continued, and thousands of us will be forced to exist under agonizing conditions day in and day out without any hope. We will work with you. We will do any work that is necessary.

I would like to read a paragraph written to us by a young woman from California:

> "In the past six months, my condition has intensified to the point where I am unable to function as a normal

> human being. Crippled with pain, I have been unable to pass the California Bar Exam, unable to work and have had to cease all sexual activity with my husband. In the past few weeks I have been bedridden with pain."

I have had IC for 3 years and live with chronic pain. Unlike many other organizations, our members are all victims of IC and are sick and unable to fight for research and treatment. There are many people more debilitated than I from states throughout the country. With great effort, I made this trip to Washington and am speaking on behalf of all those homebound, too sick to come and ask for your help. There is not one drug that can be used effectively to lessen the pain. We have thousands of women today, and men diagnosed with IC who have no where to turn to for help.

We appeal to you today to help us FIND A CURE, AND INITIATE RESEARCH THAT WOULD PROVIDE A DRUG FOR SAFE AND LONG TERM RELIEF.

WITHOUT FUNDS, WE HAVE NO HOPE. Please help us. Thank you.

In the past two years the following media have covered our efforts.

I. Books
"Interstitial Cystitis", chapter in Cooperative Approaches to Research and Development of Orphan Drugs, Liss, 1985.

II. Medical Press
Neurourology and Urodynamics (Fall '85)
Hospital Satellite TV Network (May '85)
Physicians' Radio Network (May '85)
Medical Tribune (February '85)
American Journal of Nursing (January '86)

III. Newspapers
Washington Post (September '85)
New York Times (December '84)
Philadelphia Inquirer (August '85)
New York Daily News (April '85)
City On A Hill, Santa Cruz, California (October '84)
(state journalism award for outstanding science reporting)
Syracuse Post-Standard (May '84)
Syracuse Herald (May '84)

IV. Television
NBC Today Show (April '86)
ABC Good Morning America (April '85)

Cable News Network (October '84)
WABC-TV Eyewitness News (May '85)
WNBC-TV News 4 New York (May '84 and Oct '84)
WCBS-TV Evening News (Dec '84)
AM Philadelphia TV (January '85)
WSTM-TV Syracuse News (May '84)

V. Radio
NBC Radio Network (May '85)
ABC Radio Network (May '85)

VI. Magazines
Ms. (September '85)
Working Woman Magazine (January '86)
Glamour (November '85)
Women's Health Network (Spring '85)
Women's World (September '85)
Savvy (June '86)

Senator WEICKER. Thank you very much.

Who have you been in contact with over at NIH?

Ms. SCHLOSSBERG. Dr. Striker. The two problems that we run into is that we are told that there are studies going on on urinary tract infections, urinary tract infections that some of us have had and some of us haven't in the past, so there is no relationship as we see it. It is a whole other thing, as we see it because there is the presence of infection, and it can be treated with antibiotics. When a person's, with this condition, urine is analyzed, there is no infection, so that often it is misdiagnosed, they don't know what has caused it. There are some treatments that help some, and some of the treatments are very caustic and more irritative to the bladder than when the patient went in to begin with.

So there is very little known, and most doctors around the country are not familiar with the itiology of the disease. That is the one thing that NIH says. The other studies on incontinence are being done, which again does not really help us.

The second thing that they have told us is that Dr. Parson is doing a study, but that study is just on Elmiron, which is one particular drug, which we have not had much success with, and it is only on 50 people. We would have available tomorrow thousands of women who would be glad to fill questionnaires and become part of any research project.

We would like NIH to give it a little bit more recognition. We don't have a budget to propose because we are just not on the rolls, so to speak. We would be happy for any program that is initiated.

Senator WEICKER. Thank you very much.

Ms. SCHLOSSBERG. Thank you.

Senator WEICKER. Thank you for taking the time to be here; we really appreciate it.

STATEMENT OF MARGARET A. KRIKKER, M.D., PRESIDENT, THE HEMOCHROMATOSIS RESEARCH FOUNDATION, INC.

Senator WEICKER. Our next witness is Margaret Krikker, president and founder of the Hemochromatosis Research Foundation.

Margaret, please go right ahead.

Dr. KRIKKER. Thank you very much.

I appreciate very much being able to appear before your subcommittee.

Senator WEICKER. It is nice to have you here.

Dr. KRIKKER. I am an Albany, NY, family physician, and I am also founder and president of the Hemochromatosis Research Foundation. I am here today on behalf of the foundation, which consists of physicians, patients, and 25 international advisers who are researchers and clinicians in the various disciplines which do affect this disorder.

Hemochromatosis is a disorder in which people develop arthritis, diabetes, heart problems, liver cirrhosis, cancers. Really, the book is thrown at these patients.

I am going to shorten this considerably.

Senator WEICKER. You have 5 minutes; you go right ahead.

Dr. KRIKKER. I am still going to be very brief because I have to make my plane.

I support the previous testimony, particularly the digestive disease coalition here, with respect to the funding for the NIDDK with respect to these $503 million, and we support the allocation of at least $6 billion of support for the National Institutes of Health.

Hemochromatosis is a unique disorder in that the metal, once absorbed, is not excreted, and the iron slowly and silently accumulates in the organs, the liver primarily, the heart, the pancreas, and other organs, and the joints. The symptoms are somewhat vague and do resemble many other disorders, especially when the organs become damaged.

This may be, by the way, the disorder that is responsible for women living longer than men. Women lose iron, and men, on the other hand accumulate it.

Our researchers are responsible for the major contributions of the research that has come through in the past 10 years. With the advent of biomedical and genetic research tools, we were able to determine that this was a recessive disorder, which means that both parents have to be carriers. On the basis of our research and study of pedigrees of families with this disorder, it was possible to estimate that in this country we may have anywhere between 600,000 and 1,600,000 affected Americans. Most of these people do not know they have this disorder. They may have arthritis, heart disease, diabetes, and other hormonal deficiencies, and enlarged livers. But most physicians still consider this disorder rare, so that they are not getting specific treatment for their disorders.

The disorder is unique in that this can be diagnosed early, even in childhood, and if it is diagnosed and treated, a full life span is possible. If not diagnosed, of course, this is the disorder that contributes in large part to our current disabilities. So if there were a simple and inexpensive test, we could possibly identify the very many families who do have the disorder and treat them, and that would certainly cost contain the expenses in caring for these various disabilities.

Furthermore, it would reduce the staggering economic impact upon the families, upon welfare, government, and other agencies.

Although we have acquired much knowledge about the disorder, there are very many serious gaps. We still do not know why iron is toxic to the tissues. Iron is a very unusual substance. It is actually a poison. In the blood stream, it does not travel by itself, it is in combination with a protein, and when that is used up, the iron then gets into the organs, initially in the liver. This is why the digestive disease group has much to contribute to the work that our researchers are doing.

We have been engaged in both intramural and extramural research. I don't have the specific figures for the studies because I quite unexpectedly was able to appear here. We are engaged in a Hemochromatosis Awareness Week in New York so I have been somewhat busy.

A recent journal of the Mayo proceedings by one of the researchers emphasizes the need for work. It is headed: "Hemochromatosis—The Neglected Diagnosis." It emphasizes the fact that physicians are not aware that many patients with this disorder are just not being recognized, and there is need for much research and much funds, and I just hope that your committee will replace the cuts that have been made and appropriate more money.

Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you very much, Dr. Krikker. I appreciate it.

[The statement follows:]

STATEMENT OF MARGARET A. KRIKKER

SUMMARY OF RECOMMENDATIONS

1. It is requested that appropriations for the National Institute of Health be increased to $5,200,000,000.
2. That, since Hereditary Hemochromatosis affects multidisciplinary systems, financial support for the disorder be shared among the various National Institutes of Health involved with diseases of the heart, liver, pancreas and other hormonal glands, joints, muscle, skin and immunology.
3. It is requested that the appropriations for the National Institute of Diabetes, Digestive Disorders and Kidney Diseases for the Fiscal Year 1987 be increased to $503,000,000
4. It is requested that the appropriations for the National Institute of Health for arthritis, musculoskeletal and skin disorders for the Fiscal Year 1987 be increased to $116,000,000.

For the record, I am Margaret A. Krikker, an Albany family physician and president and founder of The Hemochromatosis Research Foundation. I would like, first, to thank you for the privilege and opportunity of testifying before your Subcommittee on behalf of the Foundation (1) for the purpose of supporting an increase in appropriations for Fiscal Year 1987 for the National Institutes of Health, and (2) to request that financial support for research in hereditary hemochromatosis (hereinafter referred to as H.H.) be continued and increased during 1987. (I do not know the amounts allocated during 1986 but, judging from the 1987 budgetary requests for the various National Institutes of Health, the appropriations will most likely be less than those for 1986).

WHAT ARE THE GOALS OF THE HEMOCHROMATOSIS RESEARCH FOUNDATION?

The Hemochromatosis Research Foundation is a not-for-profit organization, founded in 1982, for the major purposes of increasing the awareness of physicians and the public about H.H., to encourage the routine screening of Americans by physicians, in hospitals, at fairs, blood banks, or wherever possible, so as to identify H.H. individuals and their families, and to solicit funds for screenings and for research, and, with growth of the foundation, to support education of and research in iron metabolism and hemochromatosis.

WHAT IS HEREDITARY HEMOCHROMATOSIS?

I shall briefly review what H.H. is even though I am aware that the members of this Subcommittee have been made aware of the disorder by the

"Dear Colleague" letter written in June 1985 by one of your members, The Hon. Senator Alfonse D'Amato, together with The Hon. California Representative, Vic Fazio, concerning a Joint Resolution to have April 13-19, 1986 proclaimed as Hemochromatosis Awareness Week. (Due to insufficient co-sponsorship, a 1986 Awareness Week did not materialize, but I am hopeful that it will in 1987)*

H.H. is a disorder of iron metabolism in which dietary-iron absorption exceeds body needs, from birth on. Since there is no effective excretory mechanism to rid the body of iron once it is absorbed, except by bleeding, excess iron accumulates gradually and silently in the vital organs: liver, heart, pancreas, pituitary and other hormonal glands, as well as in joints, muscle and skin. Because early symptoms are non-specific and resemble those in many other medical conditions (fatigue, listlessness, weight loss, joint pains, decreased sex drive and abdominal discomfort,)early diagnosis is rarely made, unless H.H. is specifically thought of by an astute physician and the appropriate screening tests performed. An early clue, when present, is that of a tan not due to sun-exposure. More advanced symptoms are those of the organs damaged: liver enlargement (prior to the development of cirrhosis and often cancer), diabetes and other hormonal deficiencies, heart arrhythmias and congestive failure, impotence, occasionally menapause in very young women, and arthritis. Most patients do not have all these problems; symptoms are variable.

H.H. COMPLICATIONS OF UNDIAGNOSED H.H. ARE THOSE OF THE MAJOR CHRONIC DISABILITIES AND CAUSES OF DEATH IN USA

The complications resulting from a delay or a misdiagnosis of H.H. are those of the major chronic disabilities (heart and liver diseases, diabetes, cancers, arthritis) affecting Americans, and early deaths.

HOW COMMON IS H.H.?

Prior to the mid-70's H.H. was considered to be rare and to affect about 20,000 Americans. With the advent of modern biomedical and genetic research tools, however, more accurate estimates indicated that H.H. was probably the most common genetic disorder, affecting 3-8/1,000 Caucasions, and a carrier rate of 10-16%. Based on the statistics of 300,000,000 Caucasions, there may be affected 600,000 to 1,600,000 Americans -- most of whom are unaware of their genetic predisposition to load and damage their vital organs and joints with iron -- and 24 to 32 million carriers. This makes H.H. MORE COMMON THAN CYSTIC FIBROSIS (100,000 affected, with a ten million carrier population) or sickle-cell anemia (50,000 affected).

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* A New York State Hemochromatosis Awareness Week did materialize and is being commemorated this week, including a Teaching Day in Hemochromatosis Friday, April 18, 1986.

HEMOCHROMATOSIS: THE NEGLECTED DIAGNOSIS

H.H. is not only the most common genetic disorder but, as a review of the medical literature indicates, it is also another genetic disorder that is rarely diagnosed before clinically manifest, or even when clinical signs and symptoms are present, i.e., arthritis, heart disease, diabetes and other hormonal deficiencies, and enlarged liver. Sad to say, too many physicians still consider H.H. to be rare; and thefefore many patients with diabetes, heart problems, liver dysfunction and arthritis due to H.H. are not receiving essential and specific treatment to remove excess iron from their bodies, with unfortunate results of an early death sentence. In addition, blood relatives of such patients are also missing the vital opportunities of getting an early diagnosis and treatment.

In 1983, in preparation for a protocol covering a pilot screening study of apparently-healthy blood donors in the Northeastern New York region of the American Red Cross Blood Services to be conducted by our foundation, in cooperation with the regional American Red Cross services, I reviewed the area hospital records for the incidence of H.H. only to learn that my search supported the prevailing literature that preclinical and symptomatic H.H. was rarely being diagnosed. Further, the diagnosis was not being made at death either, according to my review of the New York State Health Department's Bureau of Vital Statistics for the years 1978-1982. Surprisingly, there were no deaths attributed to H.H. in any of the 14 counties of the region, with the exception of the year 1978, when seven deaths were reported: one in Albany County (that of my husband) and six others in nearby Schenectady county.

More recently, from my reviews of Foundation patient-questionnaires and my correspondence with them, they substantiate further the problems of diagnosis. There are repeated stories of diagnoses made of family members shortly before or at autopsies, of delays in diagnoses result in disabling irreversible complications.

Of relevance, Dr. Virgil Fairbanks, a Mayo Clinic researcher in iron metabolism wrote an article entitled "Hemochromatosis: The Neglected Diagnosis" appearing in the January 1986 issue of the Mayo Clinic Proceedings. Among given reasons for the neglect were that "... most clinicians still consider it (H.H.) a rare disease. Thus, hemochromatosis is often not diagnosed during life. This failure of detection is because hemochromatosis mimics other common diseases. It lurks unrecognized among patients with diabetes mellitus, congestive heart failure, 'idiopathic' cardiomyopathy, rheumatoid arthritis, alcoholic cirrhosis, or hypogonadism."..."

BUT, H.H. CAN BE DIAGNOSED BEFORE SYMPTOMS OR BEFORE ORGAN DAMAGE, AND A FULL, NORMAL LIFE POSSIBLE!

Ironically, diagnosis can be made early (even in childhood) before symotoms or before organ damage. And the prophylactic treatment of periodic bleedings (one pint as in a blood donation) will remove accumulated iron and prevent further accumulation and the resultant organ damage, and a normal, full life possible. Early treatment can also reverse existing damage, depending on of course the extent and severity of the complications present at the time of diagnosis.

FUNDING FOR H.H. RESEARCH URGENTLY NEEDED

In the last ten years, our understanding of iron metabolism of iron proteins, and the genetics of H.H. have increased tremendously. We now know that the mode of transmission of H.H. is autosomal recessive, and the gene defect responsible for H.H. has been mapped on chromosome six, on the short arm closely linked to HLA-A allele of the HLA complex. There is, however, considerable need for funds for research aimed at (1) identifying the genetic defect or defects causing the increased iron absorption and at understanding the toxic effects of iron; and (2) there is urgent need of a simple, inexpensive test with which to identify the young hemochromatosis homozygote (bearer of the two H genes derived from each carrier parent) and the carriers (inheritor of one H gene); (3) iron and immunology.

SUMMARY

1. Estimates show that H.H. is the most common genetic disorder;
2. H.H. is not generally being diagnosed
3. H.H. complications are those of the major causes of chronic disability and death of Americans, and those complications are contributory to the increasingly high cost of medical care
4. Continued and increased H.H. research appropriations are urgently needed.
5. Increased H.H. funding will benefit with knowledge about H.H., earlier detection of H.H., and will result in cost-containment of the medical care of heart disease, diabetes, disabling arthritis, liver cirrhosis and cancers.

RECOMMENDATIONS:

1. It is requested that appropriations for N.I.H. for Fiscal Year 1987 be increased to $5,200,000,000.

2. That, since H.H. affects multidisciplinary systems that financial support for the disorder be shared among the various National Institutes of Health involved with diseases of the heart, liver, pancreas and other hormonal glands, joints, muscle and skin, also immunology.
3. It is requested that the appropriations for the National Institute of Diabetes, Digestive Disorders and Kidney Diseases for the Fiscal Year 1987 be increased to $503,000,000
4. It is requested that the appropriations for the National Institute of Health for arthritis, musculoskeletal and skin disorders for the Fiscal Year 1987 be increased to $116,000,000.

WHY MY INTEREST IN HH? - PERSONAL .

Aware that my husband had an undiagnosed ailment, I resumed college and entered medical school six years after my marriage. Then, as a second-year med student studying H.H. liver slides, I suspected my husband's huge liver and symptoms (weakness, abdominal, chest and joint pains) and a tan not due to sun-exposure) could be due to H.H. My suspicious were subsequently substantiated. At that time (1946), the bleeding treatments were not yet available. By the time they were, in the early 1950's, he had extensive organ damage involving his heart, liver, pancreas, pituitary, thyroid and adrenal glands, heart arrhythmias and uncomfortable hands, feet, knees and shoulders. Then, a coronary occlusion, with cardiac arrest AND open-chest resuscitation (closed-chest massage not yet routine) miraculously recovered. This was 1956. He returned to his work as research chemist and able to continue much original work. Against medical advice, however, he returned to tennis, skiing, bicycling, hiking and lived to enjoy life for 20 years longer! And, in the last year of his life, while playing tennis on two occasions had cardiac near-fatal emergencies. His death was due to a 2nd coronary and irreversible arrest in his 70th year. His joie de vivre, his personal drive and sense of humor sustained us both...

One has to live with H.H. to appreciate the psychologic and emotional impact, the tremendous financial sacrifices, and much more.

STATEMENT OF JOHN T. FARRAR, M.D., PRESIDENT, DIGESTIVE DISEASE NATIONAL COALITION

Senator WEICKER. Dr. Farrar, why don't you introduce the members of the panel, I would like to know who they are.

Dr. FARRAR. I am John Farrar, a physician. This is Dr. Alvin Gelb, who will give his title.

Senator WEICKER. Dr. Gelb.

Dr. FARRAR. This is Dr. Don Wilson.

Senator WEICKER. Dr. Wilson.

Dr. FARRAR. Next is Dr. Clarence Legerton.

Senator WEICKER. Dr. Legerton.

Dr. FARRAR. This is Tracy Cirella, a patient.

Senator WEICKER. Tracy.

Dr. FARRAR. Dr. Donald O'Kieffe.

Senator WEICKER. Nice to have you all here. Please proceed.

Dr. FARRAR. I am John Farrar, a physician, president of the Digestive Disease National Coalition. I am also professor of medicine at the Medical College of Virginia in Richmond, and a former president of the American Gastroenterological Association.

I appreciate very much the opportunity to appear before you. I represent 20 voluntary and professional organizations, with a total membership of more 110,000 members. These members are members of constituent organizations, 20 of them, who have joined together in this coalition for the purpose of inproving the quality of care of patients with digestive disease and those who lack adequate nutrition. In this testimony, when I use the term "digestive diseases," I implicitly include disturbances in nutrition as we consider assuring good nutrition an intrinsic part of our task.

Appearing on this panel will be representatives of four constituent organizations of the coalition, and they will each speak for their own organization, as well as for the coalition. You will hear testimony about many of the specific needs of the digestive disease community.

On one thing, we all agree, we need support for the various programs of the National Institutes of Health to continue to make progress in our campaign against the ravages of digestive disease [DD].

We strongly support the figure of $503 million for the NIDDK, and $6.1 billion for the entire NIH. These figures are supported by the ad hoc group for medical research funding.

This is a very crucial year, Mr. Chairman. The President's proposed fiscal year 1987 budget risks dismantling the finest medical research establishment the world has ever known or conceived of. In the corridor, someone said, it has always been this way, I think that it is really worse this year, and it is more serious. We are not just crying wolf.

The National Institutes of Health have surpassed the expectation of almost all of us in the last 25 years, and these institutes have achieved unprecedented success in research, research training, in all medical fields. To do something to jeopardize this superb enterprise suggests a lack of understanding of the necessity for stability and continuity of the scientific community.

Let me be specific about two programs—research training and the digestive disease clearinghouse.

The training of physicians and Ph.D's for research careers in the fight against DD is seriously jeopardized by the President's budget. If the NIDDK is unable to support young scientists as they embark on a career in gastroenterological research, they will give up academic medicine, go into practice, and their research talents will forever be lost to this country. We do not get a second chance at their genius, Mr. Chairman.

At the present time, there are 15 superb applicants for career awards currently being considered by the Division of Digestive Disease and Nutrition at the NIDDK. Under current constraints, only three can be funded, and no research career development awards can be funded. Next year, it could be worse; $2 million allocated specifically for training will allow the NIDDK to keep our best young scientists in academic medicine, working on digestive disease problems.

The second program of the NIDDK which urgently needs support is the NDDEIC, the digestive disease clearinghouse. I serve as the chairman of the Long Range Planning Committee for this unit, and now serve as chairman of the executive committee of the clearinghouse advisors. This model is a very important program. It provides education to patients on how to obtain medical care, how to prevent disease, and how to cope with disease.

These patient education programs are preventative, relatively inexpensive, Mr. Chairman, and enlist many community agencies in a team effort to prevent, cure and modify diseases of the digestive tract.

PREPARED STATEMENT

Senator Weicker, please allow me to thank you and the rest of the subcommittee for your courageous efforts in this time of fiscal stringency to adequately maintain support for all of the health programs. We deeply appreciate your past support. We hope for your present support. We commend your wisdom.

Thank you.

Senator WEICKER. Thank you very much, Dr. Farrar.

[The statement follows:]

Statement of John T. Farrar

Funding Recommendations for Fiscal Year 1987
DIGESTIVE DISEASE NATIONAL COALITION

A. National Institute of Diabetes, Digestive and Kidney Disease: $499 million. This level of funding would provide a modest growth rate for the institute and provide for the stabilization of the centers programs at the institute.

B. Digestive Disease Division: $150 million of the institutes funding for the Digestive Disease Division of NIDDK. This level would represent a degree of parity among the institute priorities.

C. Digestive Disease Centers Program: $11.2 million. This level of funding would allow the NIDDK to continue the meritorious centers research grants currently being funded and fund two additional centers to study pancreatic disorders and pediatric GI diseases.

D. Clinical Nutrition Research Units: $4.2 million - maintain adequate support for Clinical Nutrition Research Units and add one more.

E. DD Advisory Board: $350,000. The outstanding efforts of the DD Advisory Board should be funded at a rate very similar to other advisory boards.

F. Epidemiology and Data System: $4.5 million. To support the substantial effort being conducted to establish liver transplant data, endoscopy data, and basic digestive data and information.

G. National Digestive Disease Education and Information Clearinghouse: $500,000. To support the current outstanding efforts to provide education and information to thousands of patients, family members and professionals concerned with diseases of the digestive system.

H. Specific Funding for Training of Research Specialists: $2 million. Allocated specifically to enable the NIDDK to keep our best scientists in academic medicine working on digestive disease problems. The DD division has 15 meritorious applicants, and under current constraints only 3 can be funded and no Research Career Development Awards can be funded.

I am John T. Farrar, a physician, President of the Digestive Disease National Coalition. I am also a Professor of Medicine at the Medical College of Virginia and a former President of the American Gastroenterological Association. I appreciate very much the opportunity to appear before you. I represent 20 voluntary and professional organizations, with a total membership of more than 45,000 members. These constituent organizations have joined together in this Coalition for the purpose of improving the quality of care of patients with digestive diseases and those who lack adequate nutrition. In this testimony, when I use the term digestive diseases, I implicitly include disturbances in nutrition as we consider good nutrition an intrinsic part of our task.

The interest of our 20 organizations are many and you will hear individually from the representatives of five our member organizations. We are of one mind, we need support for the various Digestive Disease programs at the National Institutes of Health to continue to make the progress necessary in our fight against digestive diseases.

This is a very crucial year. The President's proposed FY'87 budget risks dismantling the finest medical research establishment the world has ever known or conceived of. The National Institutes of Health has surpassed the expectations of almost all of us in the last 25 years and these institutes have achieved unprecedented success in research and research training in all medical fields. To do something to jeopardize this superb enterprise suggests a lack of understanding of the necessity for stability and continuity in the scientific community.

Let me be specific about digestive disease:

The training of physicians and Ph.D.'s for research careers in the fight against digestive diseases is seriously jeopardized by the President's budget. If the NIDDK is unable to support young scientists as they embark on a career in gastroenterological research, they will give up academic medicine, go into practice and their research talents will forever be lost to this country. We do not get a second chance at their genius.

At the present time there are 15 superb applicants for career awards currently being considered by the Division of Digestive Disease and Nutrition of the NIDDK. Under current constraints, only 3 can be funded and no Research Career Development Awards can be funded. Next year it could be worse. $2.0 million allotted specifically to Digestive Disease training will enable the NIDDK to keep our best young scientists in academic medicine working on digestive disease problems.

Another very great need is for funds to establish the National Digestive Diseases Data System. The National Commission on Digestive Diseases, in 1979, recommended the establishment of such a system for the purpose of ascertaining the national epidemiological pattern of digestive diseases. If we are to recognize the contribution of genetic, environmental, emotional and dietary factors in the causation of digestive diseases, we must determine the frequency of various diseases in various segments of the population, the rural, the aged, infants and children, industrial workers, people under stress, and the obese. We urgently need data. This was recognized by the Congress in 1985 when they authorized the Director of the NIADDK to establish the National Digestive Diseases Data system for the collection, storage, analysis, retrieval and dissemination of data derived from a patient population with digestive diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases (PL99-158). Unfortunately no specific funds were appropriated for this purpose. A starting budget of $4.8 million is strongly urged for FY'87.

An additional program I would like to endorse and advocate is the Digestive Disease Research Centers. Dr. William Silen, one of the Directors of a Center will testify later. I simply want to tell you that these are centers of intellectual excellence and they will pay handsome dividends for the health of our country and we commend you for your support of these centers. One of the officers of the Coalition recently said "Today's research is tomorrows medicine". It is certainly true. We are talking about future health, not esoterica.

A final program of the NIDDK which urgently needs support is the NDDEIC, the Digestive Disease Clearinghouse. I served as the Chairman of the Long Range Planning Committee for this unit and now serve as the Chairman of the Executive Committee of the Clearinghouse Advisors. This modest but very important program provides education to patients on how to obtain medical care, how to prevent disease and how to cope with disease. These patient education programs are preventative, relatively inexpensive, and enlist many community agencies in the teamwork to prevent, cure or modify disease of the digestive tract.

My last comment will be to urge you to do your best to maintain all critical service programs that are geared toward patient care and treatment. This includes Medicare, Medicaid and various block and categorical programs funded by your subcommittee. Mr. Chairman, please allow me to thank you and the rest of the subcommittee for your courageous efforts, in this time of fiscal stringency, to adequately maintain support for all health programs, We appreciate your support.

I am pleased to respond to any questions you may have.

STATEMENT OF ALVIN GELB, M.D., BOARD MEMBER, AMERICAN COLLEGE OF GASTROENTEROLOGY

Dr. FARRAR. Next, I would like to ask Dr. Alvin Gelb to speak.

Dr. GELB. Senator Weicker, I am Alvin Gelb, chief of the Division of Gastroenterology at the Beth Israel Medical Center in New York, and I am the governor of the American College of Gastroenterology for that district. Among my other distinctions, I was born and raised in Connecticut, and a large part of my family still lives there.

The American College of Gastroenterology has a deep commitment to clinical and basic research, and its subsequent application to the treatment and total care of patients with gastrointestinal disease.

I want to tell you this morning, Senator Weicker, about the recent past of gastroenterology, the research efforts at the NIH, and the truth that they have brought forth. If one were a Rip Van Winkle who had gone to sleep 20 years ago and woke up today, one would not comprehend what has gone on in gastroenterology over these past 20 years.

I, myself, started practicing 25 years ago. The changes that have been wrought over the past 25 years are indeed a miracle. We have experienced a miracle. I want to tell you a few of the things that have gone on. It would take me hours to go into details, but a few of the highlights.

Digestive diseases are an important part of disease in the United States. It occupies $50 billion of American expenditures; 20 million Americans have chronic digestive disease. Another 14 million Americans every year have acute digestive disease. I think that everyone in this room has had an acute digestive disease at some time, and I am sure that many people sitting have a chronic digestive disease.

Some 1 out of 10 Americans will probably have a peptic ulcer sometime during their life. There has been a dramatic change in the treatment of peptic ulcers. We have drugs now that block acid secretion, that coat the base of ulcers. The incidence of surgery and digestive cripples has gone dramatically down. The incidence of hemorrhage, perforation, and obstruction due to peptic ulcers has dramatically gone down.

In the field of gall bladder disease, we have drugs now that in some instances are capable of dissolving gall bladder stones. We have now on the research level a substance which can be injected directly into the gall bladder and can dissolve gallstones.

We have instruments now that can remove, without operation, through the endoscope, stones in the common bile duct.

In the area of small bowel disease, there have been fundamental changes. Looking at bacterial toxins, and programs from the NIH, treatment for cholera has been devised. Millions of people throughout the world have been saved from the ravages of cholera.

As a spinoff of that program, methods for the treatment of traveler's diarrhea have been developed. Who has not had a vacation spoiled by traveler's diarrhea? Now that is preventable and treatable, and so on and so on, Mr. Chairman.

The development of sonography, computerized x-ray scans, endoscopy, and geography, and percutaneous techniques, that means through the skin, have revolutionized diagnosis. Therapeutic techniques performed via an endoscope are being developed at an astounding rate.

Mr. Chairman, I want to tell you one other thing. Last year, I spent 2 months in Japan on a WHO fellowship, visiting some of their gastroenterology centers. I saw there tremendous progress first-hand. The number of articles from Japan and from other countries, particularly West Germany, are growing rapidly.

Friendly competition in medical research is to be encouraged. We all win, it is not the same as competition in automobiles, steel, shoes, and in banking. However, I would feel terrible, Senator, if the United States lost its current place as the center of modern medicine, the place that all other nations look to for leadership in medical science, and which was won through the efforts of the NIH.

We cannot take our current role for granted. If we are not careful, we could be bypassed. In the early part of this century, Germany, Austria, Vienna was the center of medical research and medical practice. Since the Second World War, it has been the United States. If we allow it, tomorrow it may be some place else.

This NIH budget is vital.

Thank you, Senator.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. We will place your statement in the record in its entirety.

[The statement follows:]

STATEMENT OF ALVIN GELB

Funding Recommendations for Fiscal Year 1987
AMERICAN COLLEGE OF GASTROENTEROLOGY

A. National Institute of Diabetes, Digestive and Kidney Disease: $499 million. This level of funding would provide a modest growth rate for the institute and provide for the stabilization of the centers programs at the institute.

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G. National Digestive Disease Education and Information Clearinghouse: $500,000. To support the current outstanding efforts to provide education and information to thousands of patients, family members and professionals concerned with diseases of the digestive system.

H. Specific Funding for Training of Research Specialists: $2 million. Allocated specifically to enable the NIDDK to keep our best scientists in academic medicine working on digestive disease problems. The DD division has 15 meritorious applicants, and under current constraints only 3 can be funded and no Research Career Development Awards can be funded.

Mr. Chairman and members of the subcommittee, I am Dr. Alvin Gelb, Chief of the Division of Gastroenterology at the Beth Israel Medical Center in New York and a member of the National Affairs Committee of the American College of Gastroenterology. The American College of Gastroenterology has a deep commitment to clinical investigation to allow for the best possible treatment and total care of patients ill with gastrointestinal disease.

I would like to devote the time allotted me to describe recent clinical advancement that has been achieved and which has a profound impact on the practice of gastroenterology. Many of the startling developments have resulted from basic research carried out at NIH, made possible through research grants provided for ~~NIH~~ and the research centers.

Digestive diseases are a major cause of disability due to illness in the United States. Approximately 20 million Americans suffer chronic digestive problems; 14 million experience acute digestive disease illness. Diseases of the gastrointestinal tract are responsible for 50 billion dollars annually in lost work, lost wages, uncollected taxes, disability and health care payments. Approximately 200,000 deaths each year are due to digestive diseases. More Americans are hospitalized with digestive problems than any group of disorders, which include the salivary glands, esophagus, stomach, liver, gallbladder, biliary tract, pancreas, small and large intestines.

Gallstones are responsible for an estimated 25 million Americans suffering from gallbladder disease which costs the American public 1.0 billion dollars in surgical expenses annually. NIDDK-funded researchers are able to provide explanations of how gallstones are formed, treated and prevented.

Research personnel have been investigating methods to dissolve stones that would avoid the cost and risk of major surgery. Recently an investigator working at NIDDK successfully dissolved gallstones in patients with a new non-surgical procedure that uses a solvent called Methyl Tertiary Butyl Ether (MTBE). The technique performed under local anesthesia involved the placement of a catheter which is actually a very thin flexible tube, through the abdominal wall into the gallbladder. Small amounts of MTBE were than injected through the catheter directly into the gallbladder. Within several hours the stones in each of the patients began to dissolve. If such an alternative to abdominal surgery for removing gallstones can be perfected, it may result both in enormous costs savings and in a safer substitute to surgery especially for those patients at high risk.

Stones which most often are found in the gallbladder can also be detected in the bile ducts. Stones found in the bile ducts may have passed from the gallbladder, may have developed spontaneously in the bile duct, may have passed down from ducts which originate within the liver, and may have been discovered as residual stones following gallbladder surgery. Stones sufficiently large may obstruct the passage of bile through the biliary ductal system with sequential complications. Consequently, stones are best removed to avoid or correct the complications that have developed. An alternative method other than surgical intervention has been introduced which will remove the stones from the bile ducts. This procedure is made possible by the use of a specially designed endoscope passed via the mouth, esophagus, stomach and duodenum to the opening of the common duct. The opening of the bile duct is enlarged and the endoscope is able to withdraw the stone. On some occasions the enlargement of the opening of the bile duct will enable the stone to pass spontaneously. Thus abdominal intervention is not required. The morbidity, the extended hospitalization will reduce the cost appreciably. An endoscopic removal of the stone is about one-third of the cost of surgical intervention for the same purpose.

As a result of intensive investigation, a considerable amount of knowledge has determined the composition of stones and the constitutents in bile that predispose to gallstone formation. As a result, medical therapy has been devised for dissolving the gallstones. Two medications have been particularly appropriate for this purpose. Chendecxycholic acid and Ursodeoxycolic acid have proven to be effective. For elderly patients or patients who represent poor operative risks this form of treatment may be preferred to surgery.

Another approach to the management of residual stones in the common bile duct has been performed by the introduction of a catheter into the bile duct through which a substance such as Monactonoin can be instilled as an alternative method to again dissolve the stones in the ducts.

Peptic ulcers have affected an estimated 4 million people in the United States. As a result of the greater understanding of ulcer formation new drugs have been introduced which have dramatically improved the treatment of peptic ulcers. One class of drugs known as the H2 blockers, of which Cimetidine and Ranitidine are examples suppress acid secretion. Another drug known as Sucralfate coats the base of the ulcer and protects from further damage by the presence of acid. An entirely new approach in ulcer research is the role of brain-gut peptides, short chains of amino acids that are found within the central nervous system and the gut. Investigators in the NIDDK have studied the effects of the brain-gut peptides and found a relation to the formation of ulcers when stress is present. As a result of the greater knowledge and increased forms of treatment peptic ulcer patients requiring hospitalization for treatment of this illness has dropped over forty percent in the past ten years.

One of the ten disabling diseases of the intestinal tract is inflammatory bowel disease which incorporates Crohn's disease and ulcerative colitis. More than two million Americans suffer from chronic inflammatory disorder of the small and/or the large bowel. IBD is a disease which is characterized by bloody diarrhea and pain. By virture of the intensive efforts by NIDDK-supported scientists creative agents in the development of IBD have been identified. Two groups of compounds, prostaglandins and leukotrienes are manufactured in the body and play a role in mediating inflammation. With this new discovery direction is provided for the development of therapy that is believed will counter the effects of the two substances. By continued investigative efforts the understanding and treatment of inflammatory bowel disease has made possible a reduction in the mortality due to illness. In 1960 over three thousand Americans died from inflammatory bowel disease. The most recent figures show that the mortality is well below 800 annually.

One of the more serious types of diarrhea is found in cholera. The mortality was exceedingly high until it was realized that the fatality was due to an excessive loss of fluid from the intestinal tract. Successful treatment was possible by the replacement intravenously of a large number of liters of fluid with appropriate electrolytes.

Lactase deficiency which is characterized by an intolerance to milk and milk products can be responsible for diarrhea, bloating and severe crampy abdominal pain. By careful and persistent investigation the cause of this disorder was revealed and as a result the defect was corrected by adding the missing enzymes into the milk before ingestion. Another cause of diarrhea attributed to malabsorption is celiac disease which has been found to be due to an allergy to a fraction of wheat protein. Investigators have proven that by eliminating the responsible substance the otherwise uncontrolled diarreha can be brought under control. Another intestinal disorder responsible for malabsorption is Whipple's disease which ultimately was attributed to an atypical bacteria which has responded successfully to the proper antibiotic treatment.

The esophagus recently has drawn a considerable amount of attention to clincal investigators who have acquired a greater knowledge of the physiology and pathology. One of the methods used in the approach to esophageal disorders is esophageal motility studies. Achalasia which is characterized by stricture formation at the distal end of the esophagus formerly was dependent upon surgery for relief, has now been found to improve by careful stretching and dilatation of the lower esophageal sphincter. Cardiospasm which is a functional disorder of the lower esophagus is now responsive to new medication therapy.

Cirrhosis is the liver disease that most commonly causes death. In addition to liver failure one of the most dreaded complications of cirrhosis is hemorrhage from perforation of dilated veins that develop in the esophagus. Emergency treatment which as proven to be highly successful in stopping the acute bleeding episode is obtained by injection of a coagulating agent into the dilated veins with the production of a clot and subsequent control of the bleeding. This relatively new form of treatment enables a more thorough evaluation to be carried out to determine what plans for lasting benefits might be provided. Not infrequently the injection of a coagulating agent will prove adequate without additional treatment. One of the other complications of cirrhosis is liver failure which is manifest by drowsiness and coma due to hepatic encephalopathy. The administration of branched chain amino acids has proven successful in ameliorating the encephalopathy.

Liver transplant has moved into a recognized form of treatment of liver diseases due to selected causes. With the better undertanding of the proper case selection and the complications following liver transplantation the survival of this dramatic procedure has increased to 80 percent.

One of the most exciting advancements in the study of colon disease has been the development of the colonscope which permits examination of the entire colon. The significant advantage of colonoscopy is the ability to detect polyps that are not recognized by the conventional barium enema. By this method the cancerous polyps and early carcinomas have been able to be removed without necessarily resorting to the surgical resection of involved bowel. The development of expertise in the management of the colonscope can readily be applied in providing prophylactic care in the surveillance of the large bowel carcinoma.

In another form of liverdisease, severe hypercholesterolemia is the result of liver impairment to remove a type of cholesterol recognized as low density lipoprotein from circulation. Elevated levels of low density lipoprotein result in coronary artery disease and in the more severe cases, death before the age of thirty. In the early stages of hypercholesterolemia due to low density lipoprotein successful management has been achieved by restricting the dietary intake of saturated fatty acids and cholesterol. NIDDK investigators have found a combination of drugs that acts to increase the uptake of the low density lipoprotein by the liver, thus decreasing its concentration in the blood and at the same time increasing the conversion of cholesterol into bile acids, producing a fifty percent reduction in the blood LDL levels.

Mr. Chairman, these are just a few of the important advances in the understanding of the mechanism responsible for the development of diseases and new therapies that have been introduced for improvement in control and attainment of successful therapy. The intensive and persistent efforts to uncover causes of disease to allow for proper treatment has been the result of the extraordinary contributions made at NIH, made possible by grants due to the funding to NIH and research centers. In order to maintain this high degree of productivity the support by federal resources becomes of paramount importance. Restrictions imposed by the current budget proposal and the Office of Management and Budget are impeding the dedicated effort of the investigators and obstructing the attainment of desired goals. The achievements of the past should not be allowed to falter because of inefficient funding.

The American College of Gastroenterology has for many years stressed the continuing need to insure an abundant supply of clinical and basic biomedical researchers. The documentation and collection of data related to gastrointestinal illness is paramount in the investigative community's efforts to recognize genetic, environmental, emotional, and dietary causes of digestive diseases. The recently established Digestive Disease Research Centers programs have been most productive and gratifying. Support is needed for continued success.

The American College of Gastroenterology strongly commends the accomplishments of the Digestive Disease Advisory Board whose strategy for the prevention and ultimate treatment of digestive diseases is well recognized. The Digestive Disease Epidemiology Data System deserves special recognition in accumulation of valuable data. Expression of appreciation should be directed to the Digestive Disease Education and Information Clearinghouse which has been a source of knowledge that is disseminated both to professional and lay organizations. This concludes my testimony, Mr. Chairman. I am pleased to respond to any questions you may have.

STATEMENT OF DONALD E. WILSON, M.D., CHAIRMAN, NATIONAL DIGESTIVE DISEASES ADVISORY BOARD

Senator WEICKER. Dr. Wilson.

Dr. WILSON. Yes, Senator, I would like to introduce myself. I am Dr. Donald E. Wilson, professor and chairman of the department of medicine at the State University of New York in Brooklyn. I am also chairman of the National Digestive Diseases Advisory Board, and it is in that context that I am testifying today.

The National Digestive Disease Advisory Board is a quasi-governmental agency that has been established by Congress in 1980 to review and evaluate the implementation of the long-range plan developed by the National Commission on Digestive Diseases in 1979, and to report annually to Congress and the Secretary of HHS on progress on recommendations for future policies and programs, and on fiscal support for digestive diseases.

Many of the Commission's recommendations have not been implemented because of budgetary restrictions. This concerns the board, particularly in light of new advances and promising opportunities some of which you have just heard.

We are aware of the current efforts to reduce Federal expenditures. However, support of efforts to reduce the economic impact of digestive diseases will be cost effective.

I would like to direct your attention to four priority areas that are concerned with the administration's proposed budget for 1987.

The percentage of funded approved individual research grants has declined from about 50 percent in 1979 to one-third in 1982, and 25 percent in 1985, with further reductions scheduled in 1986 and 1987. We have now reached the point where research of excellent quality from talented scientists cannot be funded.

Moreover, under administration proposals, the budgets of those grants funded will be reduced approximately 20 percent in 1987, after having sustained reductions of 6 percent and nearly 13 percent in 1985 and 1986. We will lose productive investigators, reduce or prevent the development of new investigators with new ideas, and hobble the ability of funded investigators to perform meaningful research.

The board recommends a total budget of $503 million for NIDDK in order to provide minimum support for research related to digestive diseases.

Second, digestive disease centers provide an excellent mechanism to focus first rate multidisciplinary research on serious health needs. Through fiscal year 1985, 12 centers were funded throughout the United States. These centers have sustained a budget reduction of 6 percent in 1985, nearly 13 percent in 1986, and are looking forward to a proposed cut of nearly 20 percent in 1987.

The purposes of establishing these centers will be contravened budgetary plans, and we anticipate that teams of investigators will be forced to disband their research efforts. Moreover, the current centers have not yet addressed several important areas, for example, pediatric research in digestive diseases, and pancreatic diseases.

Another priority, that is, the development of comprehensive centers, centers which will include, as a part of their overall efforts, health demonstration projects, and community activities, which will not be possible without new funding.

The board, therefore, recommends that an additional $2.5 million be provided to fund two additional centers, making sure that full funding will be provided to existing centers, and to provide planning funding for the development of a limited number of comprehensive centers.

Our third concern is with the development of present and future manpower. The NIDDK budget has become to restricted, that without new funds there will be a severe decline in the ability to train and support new investigators. We are clearly mortgaging our future.

The board recommends increased funding sufficient to award 10 new research career development awards in 1987.

Finally, in Public Law 99–158, Congress authorized the establishment of the National Digestive Disease Data System to collect, store, analyze, and retrieve, and disseminate data derived from our digestive disease population. Unfortunately, funds have not been appropriated for this purpose. Without this system, we cannot collect and analyze the epidemiological data essential for biomedical research, patient care, and the development of public policy.

The board, therefore, recommends that an additional $2 million be provided to support the national digestive data system.

PREPARED STATEMENT

Senator Weicker, thank you for the opportunity to present our views.

Senator WEICKER. Thank you very much, Dr. Wilson.

[The statement follows:]

STATEMENT OF DONALD E. WILSON

I am Dr. Donald E. Wilson, Chairman, Department of Medicine, SUNY Health Science Center in Brooklyn, New York, and Chairman of the National Digestive Diseases Advisory Board. I am pleased to have the opportunity of speaking to you on behalf of the Board about important accomplishments and opportunities in digestive diseases research.

Congress established the National Digestive Diseases Advisory Board to review and evaluate the implementation of the National Long-Range Plan formulated by the National Commission on Digestive Diseases in 1979 and to report annually to Congress and the Secretary of Health and Human Services on recommendations for future policies, programs, and budget requirements related to digestive diseases. Our most recent annual report will be provided to the subcommittee today. The report describes advances, opportunities, and needs in digestive diseases research.

In establishing the National Digestive Diseases Advisory Board, Congress confirmed the significance of digestive diseases as a major public health issue. Digestive diseases rank second only to cardiovascular diseases as a cause of disability due to illness in the U.S. More than 34 million Americans are affected with diseases of the digestive system, 20 million of whom have chronic disorders. These diseases include more than 40 acute and chronic gastrointestinal conditions, ranging from common illnesses such as gallstones, diarrhea, and hemorrhoids to more serious, often life-threatening diseases such as liver cirrhosis, inflammatory bowel disease, and cancer. Digestive diseases are a leading cause of hospitalization and the primary reason for major surgery in this country. Together, digestive diseases represent 10 percent of the total economic burden of disease in the U.S.

Advances in biomedical research have expanded our understanding of the development of digestive diseases and consequently improved our ability to diagnose and treat these diseases, often preventing recurrence of symptoms or serious complications. The treatment of a variety of digestive diseases such as peptic ulcers, gallstones, and infectious diarrhea has improved markedly over the past few years. In addition, the development and therapeutic use of the flexible, steerable endoscope has improved the diagnosis and treatment of several digestive diseases and reduced the need for surgery in many cases. Such advances have begun to reduce the burden of morbidity, mortality, and health care costs associated with digestive diseases.

Despite these advances, the effort to reduce and eventually prevent digestive diseases has only begun. The long-range plan formulated by the National Commission on Digestive Diseases focused the attention of policy makers, health professionals, and the public on the widespread impact of digestive diseases on the Nation. Progress has been made toward achieving a few of the goals of the long-range plan (see attached status report on the Commission's recommendations). However, many of the Commission's recommendations have not been implemented because of budgetary restrictions. This lack of financial resources is a major cause of concern by the Board, especially in light of the new and promising opportunities for advances in the prevention, treatment, and early diagnosis of these disorders.

The Board is aware of the current effort to reduce Federal expenditures. However, support of biomedical research directed to reducing digestive diseases is a cost-effective investment that will yield considerable return in succeeding years. Therefore, the Board would like to direct the Subcommittee's attention to four priority areas of concern within the Administration's fiscal year 1987 proposal: support for individual research grants, support for digestive disease centers, support for research manpower programs, and support for the digestive diseases data system.

Digestive Diseases Research Grants: Despite the advances in digestive disease-related science, the appropriations for individual research grants in digestive diseases have not kept pace with the needs and opportunities in this area. As a result, the percentage of approved research grants that can be funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has declined steadily, from about 45 percent a few years ago to approximately 25 percent in fiscal year 1985. This rate will be reduced even further in fiscal years 1986 and 1987 under administration proposals. Similar reductions have occurred in all research programs supported by the National Institutes of Health. This trend, if continued, will significantly hinder or prevent many exciting research projects.

Research grant applications are reviewed by expert panels of scientists and ranked from 100 to 500, with the highest possible score being 100. A score of 225 or better is generally considered to reflect excellent quality. Under the Administration's budget for fiscal year 1987, the priority score cut-off for digestive diseases grants within NIDDK will be approximately 150, the lowest level in history. Many of the unfunded grants will be from talented new investigators applying for their first research grant; others will be from eminent investigators with a long history of contribution to the field. We have worked long and hard to attract such individuals to digestive diseases research. Some of these scientists may be forced to abandon their research efforts.

In addition to the problem of the low priority score cut-off, the budgets of all funded applications will be severely reduced below recommended levels. In fiscal year 1985, all grant budgets in NIDDK were reduced approximately six percent; in fiscal year 1986, budgets will be reduced approximately thirteen percent; and in fiscal year 1987, under the administration's proposals, budgets will be reduced approximately twenty percent. Under these circumstances, few scientists will be able to maintain effective research projects. Digestive diseases research will be severely hindered if additional funds are not provided for individual research grants.

- The Board recommends a total budget of $503 million for NIDDK to provide a minimum level of support for individual research grants and for other NIDDK programs related to digestive diseases.

Digestive Diseases Research Centers: Our second area of concern is for the recently authorized program of digestive diseases research centers. This program enables clinical and basic scientists to join together in a coordinated multidisciplinary approach to the complex research problems posed by digestive diseases. In fiscal year 1984, the Congress provided sufficient funds to establish six new digestive diseases (DD) research centers. In fiscal year 1985 four additional DD centers were established to bring the total number of DD centers funded by the NIDDK to twelve. These DD research centers are located throughout the United States.

In fiscal year 1985 all centers received a budget reduction of 6 percent from the amount recommended by the peer review study sections. Similarly in fiscal year 1986, all centers are to have budget reductions of 13 percent. In fiscal year 1987, the administration's proposal would reduce each budget by 20 percent. These reductions will seriously impair the research efforts within each center, newly established collaborative efforts will be hampered, and valuable personnel will be lost. The purpose of establishing these research centers will be contravened by the proposed budget plan. Furthermore, it can be anticipated that some newly established teams of investigators may be forced to disband their research into the causes and treatments of diseases and disorders of the digestive system.

The present portfolio of center grants does not yet include research activity in two areas designated by the Board as needing attention, viz., pancreatic disorders and pediatric digestive diseases research. These two areas appear to be ready for a level of effort that a center could bring to research in these two important, but neglected fields. In addition, some of the DD centers appear to be ready for development into comprehensive centers, that is, centers which have a component of health demonstration projects and community activities together with the research component. In order to assure the orderly development of these components in existing research centers, funds are requested to provide planning grants for this purpose. A limited number of comprehensive centers in DD are anticipated.

- The Board recommends that an additional $2.5 million be provided for two additional digestive diseases centers; for planning grants for a limited number of comprehensive centers; and for full funding of existing centers at recommended levels.

Digestive Diseases Research Manpower: Our third area of concern is for digestive diseases research manpower. Excellent award mechanisms are available to support promising young investigators. However, the NIDDK budget for training grants and individual career development awards has become so restricted that we anticipate a very severe decline in capacity to support future candidates. There are 3 types of individual career development award mechanisms used by NIDDK to support digestive diseases research. Two of these, the Clinical Investigator Award and the Physician-Scientist Award are key to providing adequate opportunity for M.D.'s to acquire sufficient research training and experience to become qualified as independent investigators. The third mechanism, the Research Career Development Award, enables the young established investigator, either Ph.D. or M.D., who is otherwise burdened with non-research academic duties, to be dedicated entirely to research during a very crucial stage of career development. Under current constraints, very few awards will be made.

- The Board recommends increased funding for the research career development of M.D.'s and Ph.D.'s in basic science areas related to digestive diseases to permit 10 new awards in fiscal year 1987.

Digestive Diseases Data System: Our fourth area of concern involves the establishment of the National Digestive Diseases Data System recommended by the National Commission on Digestive Diseases and authorized by Congress in P.L. 99-158. The data system will provide an ongoing mechanism to collect and analyze the epidemiologic data essential for biomedical research, patient care, and public policy. The first step is to ascertain the natural incidence and prevalence of defined digestive diseases. P.L. 99-158 authorized a National Digestive Diseases Data System to collect, store, analyze, retrieve, and disseminate data derived from a patient population with digestive diseases for the purpose of detecting individuals at risk of developing digestive diseases. Unfortunately funds have not been appropriated for this purpose.

- The Board recommends that an additional $2 million be provided to support the National Digestive Diseases Data System.

We appreciate your support for digestive diseases and your efforts to improve the nation's health. Thank you for the privilege of appearing before your Subcommittee. I will be pleased to respond to any questions you may have.

STATUS OF THE RECOMMENDATIONS
NATIONAL COMMISSION ON DIGESTIVE DISEASES
(Recommendations published January 31, 1979)

Recommendations 1 through 10 proposed actions that were considered to yield results in the immediate or near future.

1. Establish a National Digestive Diseases Education and Information Clearinghouse (page 17)

A National Digestive Diseases Education and Information Clearinghouse (NDDEIC) should be established under the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) to serve as a national educational resource for patients with digestive diseases and their families, physicians and other health professionals, and the general public, especially its neglected segments, such as rural Americans, the elderly, minority groups, and children. It should be funded separately from other ongoing activities of the Institute. However, NIAMDD should seek ways of having the NDDEIC work economically with the arthritis and diabetes clearinghouses.

The Clearinghouse has been established within the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK). It serves as a central resource to promote exchange of information between professional and voluntary health organizations. The Clearinghouse shares support services, and a Combined Health Information Database, with the arthritis and diabetes clearinghouses.

2. Establish Standards in Training of Physicians (page 19)

The Fogarty International Center (FIC) of the National Institutes of Health should be provided funds to support efforts to review the requirements in teaching personnel, facilities, clinical experience, and curricula necessary to provide an adequate educational experience for physicians seeking advanced qualifications in gastroenterology. To implement this recommendation:

- Such efforts should be made in collaboration with the American Board of Internal Medicine, the American Board of Pediatrics, and the respective residency review committees.
- The conclusions should be disseminated to persons involved with the training of digestive diseases specialists and serve as a stimulus for appropriate residency review committees to propose to the Liaison Committee on Graduate Medical Education minimum standards for programs approved for training in gastroenterology.

As a corollary action, boards that qualify specialists in family practice, general pediatrics, general internal medicine, general surgery, pathology, and radiology should review their requirements pertaining to the experience necessary for treating digestive diseases.

Funds have not been appropriated to the Fogarty International Center to support this activity.

Representatives of the American Society of Gastrointestinal Endoscopy and the Council of the Federation of Digestive Diseases Societies should collaborate with the Joint Commission on Accreditation of Hospitals to establish and implement requirements for training and experience that would qualify practitioners to perform endoscopy in the hospital setting and to insure that their competence in the use of the procedure is reviewed by involved medical staffs.	
3. Strengthen Professional Education in Digestive Diseases (page 20) The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) should be authorized to strengthen educational programs in digestive diseases in medical schools, and funds should be appropriated for this purpose. • Twelve digestive disease teaching awards in the first year, 14 in the second, and 16 in the third, analogous to those in the field of pulmonary diseases, each valued at up to $30,000 per year, should be established. • Funds for faculty from other institutions should be provided to supplement teaching programs pertaining to digestive diseasees in the basic science and clinical departments of medical schools where faculty involvement or expertise in digestive diseases is lacking. • Teaching programs that focus on the psychosomatic aspects of digestive diseases should be encouraged and should constitute a significant proportion of total instruction in gastroenterology. Three annual workshops should be held on educational strategies in the behavioral aspects of digestive diseases, jointly sponsored by NIAMDD and the National Institute of Mental Health (NIMH).	Funds have not been appropriated for this purpose.
4. Standardize Terminology and Diagnostic Criteria (page 22) The Fogarty International Center (FIC) of the National Institutes of Health should be provided funds to support workshops on digestive diseases to standardize nomenclature, diagnostic criteria, diagnostic methodology, and measures of functional disability. The workshops should be held in collaboration with concerned Federal agencies, national professional groups, and international bodies. The published proceedings of the workshops should be disseminated to persons concerned with research, patient care, patient bill-	Funds have not been appropriated to the FIC for this purpose. However, members of the National Digestive Diseases Advisory Board (NDDAB) and NIDDK staff have reviewed the International Classification of Diseases (the 8th and 9th editions) and identified numerous digestive disease-related codes not previously identified as such. Dr. Johannes of NIDDK subsequently developed a system to cross index these digestive disease codes. The Board has encouraged the completion and publication of this system.

ing forms, and insurance data. Advice and assistance should be sought from the American Medical Association's Committees on Current Medical Information Terminology and Current Procedural Terminology, the World Health Organization, and from medical record societies.	
5. Aid Physicians in Constructing Sequences of Diagnostic Tests (page 22) The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) should support research directed at aiding practicing physicians in making proper sequences of diagnostic tests for specific conditions in order to spare the patient unnecessary tests and to achieve cost containment.	No related research has been undertaken by NIDDK. Expensive clinical trials would be required in many instances. However, the NDDAB initiated an effort to develop a mechanism that could substitute for clinical trials in some instances. The NDDAB's model involved the application of decision analysis to screening high-risk populations for colorectal cancer.
6. Expand Translational and Clinical Health Services Research (page 23) The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), the National Institute of Allergy and Infectious Diseases (NIAID), the Center for Disease Control (CDC) and other concerned Federal agencies should increase their support for clinical health services studies and translational research in digestive diseases-related areas.	Funds have not been appropriated to any of the cited agencies to support this recommendation.
7. Strengthen Digestive Diseases Programs in the Department of Defense (page 25) The Department of Defense should receive support to enlarge its program in digestive disease research and training.	Funds have not been appropriated for this recommendation.
8. Encourage the Role of the Veterans Administration in Digestive Diseases Research (page 25) The Veterans Administration (VA) should be encouraged to: • Continue and expand its clinical research and clinical trials in digestive diseases. • Establish a special program in Veterans Administration Hospitals for diagnosis and treatment of common digestive diseases, especially those associated with alcoholism and drug abuse.	The Veterans Administration has not received additional appropriations for programs targeted toward diabetes.
9. Support Training Programs in Digestive Diseases Research (page 26)	Appropriations for training programs have not been increased; recent appropriation trends are toward fewer awards.

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), the National Institute of Allergy and Infectious Diseases (NIAID), and the Center for Disease Control (CDC) should receive additional funds for, and the National Cancer Institute (NCI) and the Veterans Administration should be encouraged to strengthen, their training programs in research in digestive diseases.

10. Expand Applied (Clinical) Research in Digestive Diseases (page 27)

Appropriations of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Aging (NIA), and the Center for Disease Control (CDC) should be increased substantially to permit expansion of the resources allocated to research applied to digestive disease problems. The increase recommended is designed to take advantage of the great opportunities available now, as identified in the research reports submitted to the Commission. The increase would expedite the rapid transfer of biomedical and behavioral research to the problems of patient care. The Commission recommends primary emphasis on investigator-initiated research grants as the mechanism of support for these activities.

The institutes listed above and the National Institute of Child Health and Human Development (NICHD) should coordinate their efforts to stimulate research activity in digestive diseases.

In order to responsibly administer the research programs recommended in this report, 16 additional staff positions in the first year, 24 in the second year, and 28 in the third year should be authorized for the extramural program in digestive diseases at NIAMDD.

Appropriations for digestive diseases research projects have increased an average of seven percent per year since 1979 (based on 1979 constant dollars). However, the percentage of approved research applications that can be funded declined from approximately 45 percent in 1979 to 25 percent in 1985.

The recommended staff positions have not been provided. In fact, overall staff positions within NIDDK and other NIH institutes have decreased significantly in the past two years.

Recommendations 11 through 16 focused on the generation of new knowledge through research, to facilitate the advancement from "halfway" technology to high technology.

11. Expand Basic Research in Digestive Diseases (page 37)

Future progress in digestive disease depends in many instances upon the solutions to fundamental biological questions. The Commission recommends that the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMMD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the National Institute of Child

Comments for #10 applicable here also.

Health and Human Development (NICHD) increase their support of basic research in biomedical and behavioral sciences related to digestive disease. Expansion of basic research is the starting point for a continuum which extends to future improvements in health care.

12. Support Cooperative Research
(page 40)

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) should fund increased cooperative research efforts in digestive diseases.

The establishment of digestive diseases research centers is related to this recommendation. These centers provide a unique mechanism for interdisciplinary and collaborative research.

13. Expand Intramural Research at the National Institutes of Health
(page 41)

The intramural research program in digestive diseases of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMMD) should be increased by 18 positions to permit recruiting over a 3-year period of 6 additional senior investigators, 6 clinical or research associates, and 6 support personnel.

One senior investigator position and one support position should be added to the intramural research program at the National Institute of Allergy and Infectious Diseases (NIAID) to enable expanded research efforts in hepatitis.

One senior investigator position and one support position should be added to the digestive disease-related intramural research program at the National Cancer Institute.

The recommended staff positions have not been provided. In fact, overall staff positions within NIDDK and other NIH institutes have decreased significantly in the past two years.

14. Determine Epidemiological Patterns of Digestive Diseases (page 42)

The National Center for Health Statistics (NCHS) should revise its presentation of data by bringing together data on all individual diseases identified by the Commission as digestive diseases to present a comprehensive picture of their prevalence and impact on the physical, emotional, and financial well-being of all Americans.

This revision should permit determinations of geographical patterns of illness and rate of occurrence among infants, children, adolescents, and adults of various ages.

The National Center for Health Statistics and the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMMD) should collaborate in studies to ascertain the prevalence of specific major digestive diseases in suitably selected populations groups.

The Board supported three epidemiologic studies related to the prevalence and impact of digestive diseases (see Annual Report). The Centers for Disease Control and the Health Care Financing Administration assisted in two of the studies. The NIDDK is developing a National Digestive Disease Data System to continue the collection and analysis of related data.

The National Institutes of Health, the Center for Disease Control (CDC), and other concerned Federal agencies should expand their funding of epidemiological studies of digestive disorders and the training of additional epidemiologists. Relevant areas of study should be identified through workshops.

15. Investigate the Toxicity of Environmental and Industrial Pollutants to the Digestive Tract (page 43)

The National Institute of Environmental Health Sciences (NIEHS), the National Institute for Occupational Safety and Health (NIOSH), and concerned lay organizations (such as industry and labor groups) should increase their efforts to collect and disseminate comprehensive data on hepatic and gastrointestinal injury caused by exposure to industrial and other environmental chemicals.

All concerned public and private agencies should give priority to the support of research in the pathogenesis, detection, prevention, and treatment of the injurious effects of industrial and environmental pollutants on the digestive organs.

Study of the following topics should be emphasized:

- Toxicologic and metabolic investigations, including absorption, metabolism, and elimination of chemical agents.
- The influence of nutrient deficits, smoking, consumption of alcoholic beverages, and use or abuse of various drugs on the toxic effects of industrial and environmental pollutants.
- Development of sensitive, specific, simple, noninvasive tests for detection of injury to the liver and other organs that may be applied in mass surveillance of workers in industry.

No known initiative has been undertaken in this area.

16. Study the Influence of Nutrition on Susceptibility to Digestive Diseases (page 44)

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMMD), the National Institute of Child Health and Human Development (NICHD), and the National Cancer Institute (NCI) should assign high priority to and be funded for long-term laboratory, clinical, and epidemiological research in the role of diet in the causation of digestive diseases.

No specific activities have been initiated. Existing Clinical Nutrition Research Units support related activities but the degree of specific digestive disease related research in those units is not known.

Recommendations 17 through 20 apply to general improvements in health care, with specific implications for digestive diseases.

17. Study Continuing Medical Education and Assess Manpower Needs (page 45)

Funds should be appropriated to the Health Resources Administration (HRA) for research to:

- Cosponsor with appropriate professional organizations a continuing study of the need for and current supply of digestive disease specialists in practice, research, teaching, and full-time academic positions.
- Study the relationship of quality of care and cost-effectiveness of medical care to the type and level of training of the health professional providing the care.
- Determine manpower requirements, curricula, educational facilities, duties, certification, licensing, and responsibilities of nonphysician health professionals.
- Investigate whether costs are lowered through the use of nonphysician health professionals and, if so, recommend third-party reimbursement procedures to promote fuller use of the health professionals (see Recommendation 18).

The Health Resources Administration, in collaboration with the proposed National Digestive Diseases Education and Information Clearinghouse, should support evaluations of the effectiveness of various teaching methods used in continuing medical education in digestive diseases.

Funds have not been appropriated to support this recommendation.

18. Provide health Insurance Coverage for Patient Education (page 46)

The cost of educating patients about their digestive diseases, within the context of other aspects of medical care provided by both physicians and other health professionals, should be treated as a distinct reimbursable expense to be paid by medicare, Medicaid, and future government-financed health programs (see Recommendation 17). Private third-party carriers should be encouraged to follow this policy.

No progress has been made toward this recommendation.

19. Provide Health Insurance Benefits for Catastrophic Diseases (page 47)

Legislation should be enacted to provide insurance benefits to defray the catastrophic expenses (as defined by Congress) of major illness, including digestive diseases.

No action. However, the subject receives frequent Congressional interest and the Secretary, DHHS, revently gave high priority to the development of legislation to provide insurance benefits for catastrophic expenses of major illnesses.

20. Facilitate Progress in Digestive Diseases by Administrative Changes (page 48)

The Federal Office of Management and Budget (OMB) should exempt from its forms clearance requirements and procedures any medical and related behavioral research projects that are:

- Conducted in accordance with protocols that specify in advance the problem(s) to be addressed, the number of respondents required, the information to be collected from them, and the expected duration of the study.
- Covered by and approved under the Department of Health, Education, and Welfare regulations for the protection of human subjects (45 CFR 46).
- Based on voluntary participation by the respondent population.

An exemption from the policy of the Department of Health, Education, and Welfare to reduce conferences should be granted to conferences and/or workshops outlined in the long-range plan to combat digestive diseases.

No action.

Recommendations 21 through 23 are aimed at coordinating components of the national long-range plan.

21. Establish a National Digestive Diseases Advisory Board (page 49)

A National Digestive Diseases Advisory Board should be established to review, advise on, and facilitate coordination of Federal activities in digestive diseases. It should report directly to the Congress and the Secretary of the Department of Health, Education, and Welfare (DHEW).

The Board was established in October 1981 pursuant to P.L. 96-538. The Board was reauthorized in P.L. 99-158.

22. Ensure Representation for Digestive Diseases on Three Institute Advisory Councils (page 50)

The National Cancer Institute (NCI), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Alcohol Abuse and Alcoholism (NIAAA) should have on their advisory councils at least one individual with specialized knowledge of digestive diseases.

Digestive disease specialists are on the NCI, NIAID, and NIAAA Advisory Councils. In addition, the Board has directed its attention to the composition of the scientific review panels at the National Institutes of Health responsible for the evaluation of all research grant applications relevant to digestive diseases.

23. Provide Identity and Visibility to Digestive Diseases Within the National Institutes of Health (page 50)

Administrative measures should be undertaken by the National Institutes of Health (NIH) to emphasize the importance of the digestive diseases and to provide budgetary identity.

This recommendation was accomplished through the establishment of the Division of Digestive Diseases and Nutrition within NIDDK.

STATEMENT OF C.W. LEGERTON, M.D., CHAIRMAN, COMMITTEE ON PUBLIC POLICY AND GOVERNMENT RELATIONS, AMERICAN GASTROENTEROLOGICAL ASSOCIATION

Senator WEICKER. Dr. Legerton.

Dr. LEGERTON. Thank you, Mr. Chairman. I am Clarence Legerton, and I am from Charleston, SC. I am professor of medicine at the Medical University in Charleston, rather than Columbia. We have two schools.

It is my privilege to represent and to speak for the American Gastroenterological Association, which is an organization, as you know, Senator Weicker, that represents almost 5,000 physicians who are interested in the patient care and research in the field of digestive diseases.

We are very aware of the support that you, as chairman, and other members of the committee, have given to research in digestive diseases, and in our field, and we are certainly very appreciative of it.

We also would like to thank you personally for the work that you are doing to increase funding in the budget so that the appropriation for the NIH will be increased. We think that it is vital.

Unfortunately, as you know, and the other speakers have brought out, we have had a serious decline in overall research dollars available to the NIDDK and, of course, that translates into less dollars for the division that we are interested in, digestive diseases and nutrition.

In 1985 the figure was a little in excess of $91 million. In 1986, it fell to in excess of $85 million. In 1987, it is slated to drop to $83,328,000. So it is declining considerably, and we do face some real concerns in this area. So we would ask, Mr. Chairman, that you reject the administration's budget as it would seriously reduce research in our field, and cut it about 19 percent.

The major issue that we would like to address this morning, and we think is of true crisis proportion, is that of research manpower in gastroenterology.

Since 1968, the total of all NIH trainees in digestive diseases has been dropping very rapidly. Simply put, we really need an influx of bright, intelligent young men and young women to come into the field of research of digestive diseases, because without them, we can certainly expect to have a drop off in the progress that we have made in recent years in the research in our area.

The total number of research awards, as I am certain you know, has been dropping steadily. In 1984, there were 40 such awards. In 1985, it dropped to 37. The estimate for 1986 is only 26 of these awards. You heard Dr. Farrar say that there are 15 highly qualified applicants for it, and yet only 3 can be funded.

According to the primary recommendation of the American Gastroenterological Association is that funding be increased for the career development of physicians and basic scientists to enable us to have 10 new awards in digestive diseases, and 5 awards to the field of nutrition.

The other major interest, and the last one that we have, is in digestive research centers. You have heard Dr. Wilson speak eloquently about them.

With the help of you and your committee, and other Members of Congress who have been immensely supportive, we now have 12 centers. One of these is in that very prestigious institution, Yale University, which last I heard was in Connecticut. I think that it is still functioning extremely well. But they are spread all across the country, all the way from Harvard and Yale, out to the University of California.

These centers, as you know, produce remarkable avenues for collaborative research in basic and clinical sciences in established areas of excellence such as Yale. Yet the proposed funding cuts would seriously impair research efforts in these centers.

If you have cuts of about 20 percent, obviously, you are going to lose personnel, you are going to have diminished opportunities for research, and the output of research by teams of very able investigators will certainly decline.

So we would urge the Congress, as Dr. Wilson said, to restore center budgets to full budget amounts as recommended by the study section, and to give us a small amount of money to initiate planning grants for the development of a very limited number of comprehensive digestive disease centers.

I would like to reiterate what Dr. Farrar and Dr. Wilson have said with regard to the centers and the tremendous opportunities that they offer for research, and to hope that they can continue to be supported.

We do very much appreciate what you and the committee have done, and we thank you for it.

PREPARED STATEMENT

Senator WEICKER. Thank you, Dr. Legerton, I appreciate it very much.

Dr. FARRAR. Mr. Chairman, might I ask Tracy Cirella and Don O'Kieffe to come over and sit facing you.

Senator WEICKER. All right.

Dr. FARRAR. She is our next witness.

[The statement follows:]

STATEMENT OF C.W. LEGERTON

Mr. Chairman, I am Clarence W. Legerton, M.D., Professor of Medicine at the Medical University of South Carolina at Charleston.

I represent the American Gastroenterological Association which has over 4,000 physician members concerned with the improvement of patient care and research in the field of digestive diseases.

Mr. Chairman, this Committee has long been supportive of the research in the field of digestive diseases, and once again we thank you deeply for that.

We understand that at hearings earlier this year, when the Administration witnesses and the National Institutes of Health officials presented, the level of frustration of the Members of this Committee with the proposed Administration budget mirrored our own frustration.

You will see at the end of this testimony a chart which indicates the serious decline in research dollars available to the National Institute of Diabetes, and Digestive and Kidney Diseases overall (less the amounts for the new Arthritis, Musculoskeletal and Skin Institute), as well as the decreased dollars available for the Digestive Diseases and Nutrition component of this institute.

If you will look at that bottom line you will note that the figures for digestive diseases research in fiscal year 1985, fiscal year 1986 after the sequestrations of the Gramm-Rudman-Hollings Act, and the proposed rescissions, and other administrative adjustments, and the proposed fiscal year 1987 Administration budget, all show a precipitous decline for research in this field. The comparable figures are:

FY 1985 - $91,238,000
FY 1986 - $85,789,000
FY 1987 - $83,328,000

Of course, Mr. Chairman, we recognize that under this Committee's leadership the Congress rejected the proposed rescission, so that in fact the total dollars for fiscal year 1986 will be slightly higher than those indicated.

Nevertheless, even with those amounts restored, the fiscal year 1986 budget will be seriously below the fiscal year 1985 budget.

We urge you to reject the Administration's proposed budget out of hand, as it would result in a decrease of nearly 9% below the fiscal year 1985 levels. If you add in an inflation factor of at least 5% per year (the biomedical research deflator), you will find that if the Administration's budget proposal for fiscal year 1987 would be agreed to, there would in fact be a loss of nearly 19% of research done in this field.

It is unfortunate that the Administration proposes these decreases at a time when the field of digestive diseases and nutrition research is burgeoning, especially because of the strong support given by this Committee in recent years to the digestive diseases research centers.

It is not necessary to go into detail here about the various research advances that have been occurring, as it is our understanding that this Committee held comprehensive hearings on that matter and have received information from the Institute about advances now being made.

Because of the shortness of time available to us, Mr. Chairman, resulting from the pressures that you are under given the new budgetary scheduling requirements, rather than dwell on the rapid advances that are being made in our field, I would prefer to talk about the structures that support some of these areas of investigation.

RESEARCH MANPOWER

Mr. Chairman, many of my colleagues believe we face a real, not imagined, crisis in research manpower in digestive diseases research.

Our studies show that since 1968, the total of all NIH trainees in digestive diseases research has been dropping steadily. This trend, in combination with the confusion that has existed for more than a decade in the public policy debate over research funding, and the further exacerbation caused this year by the cuts required by Gramm-Rudman-Hollings, causes us very serious concern about the future research enterprise in digestive diseases.

Simply put, without a continuous influx of highly motivated and intelligent young people into our field, we can expect with certainty slower research progress than would otherwise be possible.

I would like to describe the background of the situation, indicate the specific issues which concern us, and make recommendations to this Committee to deal with them.

Background

Research career development: there are 3 types of career development award mechanisms used by the Division of Digestive Diseases and Nutrition (DDDN) in the support of the digestive diseases research community. Two of these, the Clinical Investigator Research Award (CIA) and the Individual Physician Scientist Award (PSA) are key to providing adequate opportunity for M.D.'s to acquire sufficient research training and experience to become qualified as independent investigators. The third mechanism, the Research Career Development Award, is of particular importance in the support of both Ph.D.'s and M.D.'s working in the areas of basic science that are the underpinning of studies on digestive diseases research training following medical and early research training and up to the time in the physician's career when research support through the traditional NIH research project grant becomes reasonable. The RCDA enables the young established investigator, who is otherwise burdened with non-research academic duties, to be dedicated entirely to research during a very crucial stage of career development.

Research training: the National Research Service Award (NRSA) provides individual postdoctoral fellowship support and research trainee positions through institutional training grants. This stage of training support is vital to the continued availability of well-trained researchers in digestive diseases. Notably, it provides a training link between an M.D.'s clinical training and the stage where that person can qualify for a CIA. NRSA support is essential to maintaining a pool of physicians both qualified and motivated to staff the Nation's medical schools.

Issues

The research career award budget has become so restricted that we anticipate a very severe decline in capacity to support career award candidates in digestive diseases. There are 15 applicants for career awards currently being considered by the Division of Digestive Diseases and Nutrition (DDDN) for support who have priority scores of 155 or better: viz., 2 for RCDA's, 4 for PSA's and 9 for CIA's. Of these 15 applicants, DDDN can plan to fund, under current constraints, 3 PSA's (see Table 1). The number of NRSA awards funded in digestive diseases has remained relatively constant (see Table 2); however, the Institute of Medicine in its 1985 report 'Personnel Needs and Training for Biomedical and Behavioral Research' urges an increase in NRSA support to meet projected needs of academic medicine.

Table 1. Numbers of research career awards in digestive diseases, Fiscal Years 1982-1985 and 1986 estimate. (K04 = Research Career Development Award, K08 - Clinical Investigator Award, K11 = Physician Scientist Award).

	Mechanism			
Fiscal Year	K04	K08	K11	(Total)
1982	21	12	N.A.	33
1983	17	18	N.A.	35
1984	19	21	0	40
1985	15	21	1	37
1986 (est)	12	11	3	26

Table 2. Digestive diseases National Research Service Awards, individual postdoctoral fellowships and estimates of trainee slots on institutional training grants, Fiscal Years 1982-1986.

Mechanism	Fiscal Year 1982	1983	1984	1985	1986
Trainees on Institutional Training Grants	106	114	118	121	110
Postdoctoral Fellowships	22	33	30	29	29

Recommendations

1. Increase funding for the career development of M.D.'s and in selected basic science areas, for Ph.D.'s, to enable 10 new awards in digestive diseases, and 5 new awards in nutrition each year.
2. Increase support of research training, as recommended by the National Academy of Science, through the National Research Service Award mechanism.

CENTERS

Mr. Chairman, the Congress has been extraordinarily supportive of digestive diseases centers. Since fiscal year 1984, when this Committee provided funding for six new digestive diseases research centers (there were two established previously), with an additional four established in fiscal year 1985, there are now 12 digestive diseases centers funded by the NIDDK. Attached to this testimony is a map which shows with black circles where these digestive diseases research centers are located. In fiscal year 1985, all the center grants in the NIDDK, including the digestive diseases center grants, received a reduction of 6% of the amount recommended by the peer review study sections. Then, in fiscal year 1986 the center grants will have to accept a budget reduction of 13% because of the sequestrations (though this might be modified slightly becuase the Congress has not agreed to the proposed rescissions). However, in fiscal year 1987, if the proposed Administration budget for the NIDDK takes effect, the budget for each center will be reduced by 20%.

The attached chart shows what the budget levels look like for fiscal year 1985 through fiscal year 1987, and I have included on the right hand side a level proposed for the Digestive Diseases Centers and the five Clinical Nutrition Research Units supported by this institute. You will note that the full funding of these centers, a total of $9.688 million would be required for the 12 Digestive Diseases Centers and $3.556 million for the Clinical Nutrition Research Units.

We believe that the situation could not be more starkly drawn than in these charts. If these proposed budget reductions for centers take place, the research efforts within these centers will be seriously impaired, and especially the newly established collaborative efforts will be hampered. We know that technical personnel are going to be lost and that the level of research efforts by teams of investigators are certain to decline.

RECOMMENDATION: CENTERS

We urge the Congress:

(1) to provide funds to restore center budgets to full budget amounts as recommended by study sections, if necessary inserting bill report language to bolster whatever line item figures are put into the bill; and

(2) to provide a small amount of funds to initiate planning grants for the development of a limited number of comprehensive digestive diseases centers in the future (We believe that planning on these centers, even though funds might not be available for several years, should go forward.).

We believe that there are two areas especially fruitful for research by such digestive diseases centers which presently are not covered; these include (1) pancreatic disorders and (2) pediatric digestive diseases research.

DIGESTIVE DISEASES DATA SYSTEM

Mr. Chairman, let me move to a second area of significant concern for us, and that is the national Digestive Diseases Data System.

As long ago as 1979, the National Commission on Digestive Diseases recommended to the Congress the establishment of a Digestive Diseases Data System to determine the national epidemiological pattern of digestive diseases.

Although this recommendation was made nearly seven years ago, there have never been funds to develop such a program, which is so vital in order that we can begin to draw a comprehensive plan of attack on digestive diseases.

Bill report language provided by this Committee in 1985 authorized the Director of the NIADDK to establish such a data system. That language has been repeated in your bill reports ever since. Additionally, the recently passed authorization legislation for the NIH (P.L. 99-158) lays out specific authorization for such a data system.

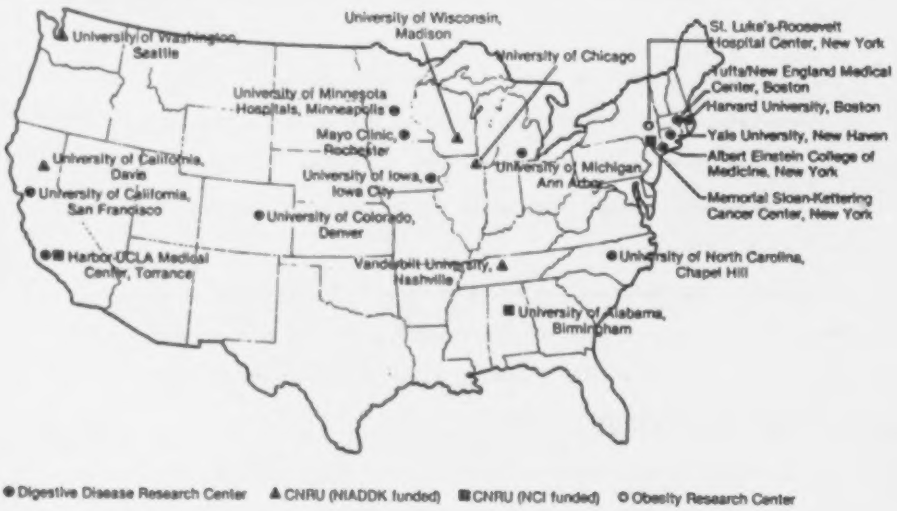
RECOMMENDATION: DATA SYSTEM

We recommend that this Committee provide funds to establish the national Digestive Diseases Data System. It is estimated that a budget of $4.5 million should be added to provide for this system.

SUMMARY

Mr. Chairman, we thank you for allowing us to appear before you again this year. We would be pleased to answer any qeustions you have, and once again we wish to express our deep appreciation to you for all of the support that you have given to biomedical research over the years, but especially that in the area of digestive diseases and nutrition.

Centers Program of the Division of Digestive Diseases and Nutrition


University of Washington, Seattle
University of Wisconsin, Madison
University of Chicago
University of Minnesota Hospitals, Minneapolis
Mayo Clinic, Rochester
University of Iowa, Iowa City
University of Michigan, Ann Arbor
University of California, Davis
University of California, San Francisco
University of Colorado, Denver
Harbor-UCLA Medical Center, Torrance
Vanderbilt University, Nashville
University of Alabama, Birmingham
University of North Carolina, Chapel Hill
St. Luke's-Roosevelt Hospital Center, New York
Tufts/New England Medical Center, Boston
Harvard University, Boston
Yale University, New Haven
Albert Einstein College of Medicine, New York
Memorial Sloan-Kettering Cancer Center, New York
● Digestive Disease Research Center
▲ CNRU (NIADDK funded)
■ CNRU (NCI funded)
○ Obesity Research Center

NATIONAL INSTITUTE OF DIABETES, AND DIGESTIVE AND KIDNEY DISEASES*

Appropriations History

FY 1985, 1986, and Proposed 1987

*FY 1985 and 1986 continue inclusion on top line of Arthritis, Musculoskeletal and Skin Programs, but FY 1987 with those deducted.

	1985	Revised 1986	Proposed Budget 1987
APPROPRIATION	$ 543,576,000	$ 569,597,000	$ 418,971,000
Administrative Reduction		-257,000	
Sequester (Gramm-Rudman-Hollings)		-24,482,000	
Rescission		-7,980,000	
	543,576,000	536,878,000	418,971,000
Transfer to New AMS Institute	-108,808,000	-109,788,000	--
Add and Subtract Various Administrative Adjustments			
Total Comparable Appropriations** NIDDK	427,968,000	429,687,000	418,971,000
Total Comparable Appropriations** Digestive Diseases and Nutrition	91,238,000	85,789,000	83,328,000

**Figures after all sequesters, rescissions and adminsitrative adjustments.

FACT SHEET

This fact sheet accompanies testimony given to the U.S. Senate and U.S. House of Representatives subcommittees on Labor-HHS-Education appropriations, during April, 1986.

The American Gastroenterological Association recommends:

1. That a major emphasis of this year's appropriations process be on digestive diseases research manpower.

   It is becoming increasingly clear that an increase in funding for the career development of MD's and in selected basic science areas for PhD's is vital to the continued influx of researchers into our field. Additionally, increased support for research training, as recommended by the National Academy of Science, is also needed.

   There are 3 types of career development awards mechanisms; two of these, the Clinical Investigator Research Award and the Individual Physician Award are key to providing adequate opportunity for MD's to acquire sufficient research training and experience to become qualified as independent investigators. The third mechanism, the Research Career Development Award, is of particular importance in the support of both Phd's and MD's working in the areas of basic science that are the underpinning of studies on digestive diseases.

   Also the National Research Service Award provides individual postdoctoral fellowship support and research training through institutional training grants.

2. We support funding of the Digestive Diseases centers at levels proposed by peer review study sections; the centers have in the past several years been cut below these levels, and if the Gramm-Rudman-Hollings cuts take place once again in FY 1987, it is probable that some of these centers will curtail activities in research significantly.

3. We support funding of the National Digestive Diseases Data System, which has been provided by appropriations bill language for several years, and last year by authorization in the biomedical research authorization legislation--it has, however, never been funded, and is vital to understanding the epidemiological pattern of digestive diseases in our nation.

4. We support the NIDDK coalition call for funding levels of $504 million for the institute in FY 1987, and support the Ad Hoc Coalition for Biomedical Research proposed levels of $6.07 billion, for all of NIH for FY 1987.

STATEMENT OF TRACY CIRELLA ON BEHALF OF THE AMERICAN LIVER FOUNDATION, AND DIGESTIVE DISEASES NATIONAL COALITION

Senator WEICKER. Tracy, you go right ahead.

Ms. CIRELLA. Good afternoon. My name is Tracy Cirella. I am 18 years old and very grateful to be alive. I am a senior at Half Hollow Hills High School in East Dix Hills, Long Island, and I coach an eighth grade girl soccer team and play badminton on the varsity team.

Last summer, I was involved in an automobile accident that almost took my life. But it wasn't the accident that threatened my life, it was a transfusion of infected blood that was the culprit.

Some internal bleeding caused by several fractures in my pelvis made it necessary for me to have a transfusion. The blood I received contained a treacherous hepatitis virus. I am sure you know that there is no screening test available to identify this particular virus in blood, nor is there any effective drug to render it harmless.

In addition, the doctors had a difficult time diagnosing what was happening to me because of the lack of appropriate laboratory tests to identify non A non B hepatitis. Just 6 weeks after my transfusion, I was deathly ill. The virus had virtually destroyed my liver and I lapsed into a coma. My only chance for survival was a liver transplant. There simply was no other treatment. My father arranged to have me flown by helicopter from Long Island to Deaconess Hospital in Boston.

Again, I am very lucky. When I was desperately in need of a liver transplant, the parents of a 15-year-old girl in Chicago, who was dying with a cerebral hemorrhage, decided to donate her organs and I received her liver.

I am also lucky because my liver transplant was successfully done by the highly skilled transplant team at the Deaconess. It was touch and go for several weeks following my surgery. My body was trying to reject my new liver and at the same time I was trying to fight off a viral infection that flared up because of the antirejection drugs I had to take. It was really scary for me and devastating for my family. They are still terribly concerned about my future with my new liver and all the medicine I will have to take to keep from rejecting it.

I am extremely grateful to be alive and talking to you right now. But, if there had been a test to screen the blood that I received or an antiviral agent to fight the hepatitis that destroyed my liver, I wouldn't have needed the liver transplant.

I came here today because I wanted my personal story to emphasize the need for more research. You hold the purse strings and can provide the funds. When you do, you will be preventing tragedies like mine and avoiding the tremendous cost of liver transplants.

My operation cost $250,000 plus an additional $30,000 that my parents spent to be with me each day during my 2½ month hospital stay. To avoid rejecting my liver, I will have to take cyclosporin every day at an additional cost of $6,000 each year. I am grateful for the medical miracle that saved my life. We can count on many more medical miracles if the dollars are made available now.

We know that 10 to 14 percent of the 4 million Americans who received blood each year will develop hepatitis. As one of those unlucky people, I ask you to please increase the funding for research to save other kids and their parents from having to go through the experience we did.

My parents and I are doing all we can to help the American Liver Foundation raise funds for liver research. But we are counting on you to provide the funds that will guarantee continued progress to save lives.

Thank you for giving me this opportunity to share my story with you.

PREPARED STATEMENT

Senator WEICKER. Tracy, thank you very much, and thank you for taking the time to encourage efforts in this regard for other people who might be in the same boat that you are in. We appreciate your coming down here.

[The statement follows:]

STATEMENT OF TRACY CIRELLA

Good morning. My name is Tracy Cirella. I am 18 years old and very grateful to be alive. I am a senior at Half Hollow Hills High School in East Dix Hills, Long Island and I coach an 8th grade girls' soccer team and play badminton on the varsity team.

Last summer I was involved in an automobile accident that almost took my life. But it wasn't the accident that threatened my life, it was a transfusion of infected blood that was the culprit. Some internal bleeding caused by several fractures in my pelvis made it necessary for me to have a blood transfusion. The blood I received contained a treacherous hepatitis virus. Do you know that there is no screening test available to identify this particular virus in blood. . .nor is there any effective drug to render it harmless? In addition, the doctors had a difficult time diagnosing what was happening to me because of the lack of appropriate laboratory tests to identify non A non B hepatitis. Just 6 weeks after my transfusion, I was deathly ill. The virus had virtually destroyed my liver and I lapsed into a coma. My only chance for survival was a liver transplant. There simply was no other treatment. My father arranged to have me flown by helicopter from Long Island to Deaconess Hospital in Boston.

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I am extremely grateful to be alive and talking to you right now. But, gentlemen, if there had been a test to screen the blood I received or an anti-viral agent to fight the hepatitis that destroyed my liver -- I would'nt have needed the liver transplant. I came here today because I wanted my personal story to emphasize the need for more research. You hold the purse strings and can provide the funds. When you do, you'll be preventing tragedies like mine and avoiding the tremendous cost of liver transplants. My operation cost $250,000 plus an additional $30,000 that my parents spent to be with me each day during my 2 1/2 month hospital stay. To avoid rejecting my liver, I will have to take cyclosporin every day at an additional cost of $6,000 each year. I am grateful for the medical miracle that saved my life. And we can count on many more miracles if the dollars are made available now.

We know that ten to 14 percent of the 4 million Americans who received blood each year will develop hepatitis. As one of those unlucky people, I ask you to please increase the funding for research to save other kids and their parents from having to go through the experience we did.

My parents and I are doing all we can to help the American Liver Foundation raise funds for liver research. But we are counting on you to provide the funds that will guarantee continued progress to save lives.

The American Liver Foundation recommends the continued support of efforts to prevent digestive diseases, to improve medical treatments and to find cures. We ask you to consider the following levels of funding for fiscal year 1987:

- National Institute of Diabetes, Digestive and Kidney Diseases - $499 million
- Conte Digestive Diseases Centers program - $12 million
- National Digestive Diseases Advisory Board - $350,000
- National Digestive Diseases Information Clearinghouse - $500,000
- Digestive Diseases Epidemiology Data System - $4.5 million

STATEMENT OF DONALD O'KIEFFE, M.D., CHAIRMAN, LEGISLATIVE COMMITTEE, AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY

Senator WEICKER. Dr. O'Kieffe.

Dr. O'KIEFFE. It is a tough act to follow.

I am Donald O'Kieffe, and I am a practicing gastroenterologist in the District of Columbia, and on the faculty of George Washington University Medical Center.

Today, I am here representing the American Society for Gastrointestinal Endoscopy, an organization with more than 3,500 members with expertise in diagnosing and treating gastrointestinal disease.

This is the fourth year I have had the opportunity and privilege to appear before this committee. The first thing I would like to do is, personally and on behalf of the American Society of Gastrointestinal Endoscopy, to thank you for your steady efforts on behalf of biomedical research and NIH funding, and your committee.

The digestive disease community is particularly grateful for the level of funding for NIDDK, and specific language for digestive diseases, especially the centers program, over the past few years.

I know that the message has been heard, and I know that you have heard the message. The message has been given by countless individuals to this and other committees on the Hill, namely, that medical advances that we, as a society, enjoy today have their roots 5 or 10 years ago. Likewise, the health care that is going to be given to American citizens 5 or 10 years from now will be affected by today's decisions, including some of the budgetary issues in front of this committee.

We are fully aware of the constraint on this committee by the need to reduce the Federal deficit. I can only urge that the budget proposals that the various digestive disease organizations are presenting today and agree on be given strong consideration during your deliberations.

These specific proposals have already been mentioned, including funding for the digestive disease centers program, and the data system. They are listed in my prepared testimony, and I would like to submit that for the record.

In the past several years, I have brought either an endoscope or a small toposcopic catheter, something to basically give you a hands-on, firsthand view of some of the advances within the endoscopy world. I discussed with you the beneficial spinoffs of these advances for the American public.

This year, I was a little hesitant to challenge the imagination of the security people at the front door. Their skeptical looks last year when they were going through this equipment made me think twice about trying to get it in this year.

At any rate, what I would like to do for the last few minutes is to briefly discuss one subject which I think exemplifies the potential marriage between primary research, fiber optics, and the prevention of a serious health problem in the United States, and I am referring to cancer of the colon.

This subject, which has been a very important health issue in the United States, has achieved increased visibility and attention since the President's surgery, accounting for 135,000 new cases, and 65,000 deaths. It is the second leading malignancy in our society.

However, what we now know and understand about cancer of the colon allows us to at least imagine today when this cancer might be eliminated. We feel that almost all cancer of the colon begin in previously benign colon polyps. With the use of fiber optic instruments, we can detect and remove these polyps without hospitalization or surgery, thus interrupting the sequence that goes on to cancer.

All we need to do is to discover, hopefully in an economic fashion, those patients with polyps or a strong predisposition to polyps. This is where NIH and NIH grants enter the picture.

Researchers at the various institutions, including the National Institutes of Health, are working on blood in stool tests which could be economically administered on a mass screening basis to detect those individuals who then should be studied further in terms of possibility of having colon polyps.

At the same time, important research into possible dietary and genetic factors responsible for polyp genesis is also going on.

Thus, with these newer concepts of the natural history of colon cancer, coupled with a clear understanding of the epidemiology of the illness, we are poised to launch a frontal attack on the problem. If monoclonal antibodies, or some other laboratory technique becomes available to detect the population at risk, fiber optic technology already exists to do the rest.

Realistically, we should be able to greatly reduce the incidence of this second most common cancer in our society. Much of the credit for what we are seeing today can be traced to legislation and funding of previous congresses. We who represent the Government issue community today hope that the strong funding and bill report language will continue to be forthcoming.

Thank you for the opportunity to be here today.

Senator WEICKER. Dr. O'Kieffe, thank you very much.

I thank each one of you for making the effort and taking the time to appear. You just keep on talking, and we will try to do our job.

Dr. FARRAR. Thank you very much.

[The statement follows:]

STATEMENT OF DONALD O'KIEFFE

Mr. Chairman, I am Donald O'Kieffe, a practicing gastroenterologist in the District of Columbia and a faculty member of George Washington University Medical Center.

I represent the American Society of Gastrointestinal Endoscopy, an organization of more than 3,000 gastroenterologists and surgeons who specialize in the diagnosis and treatment of diseases of the digestive tract.

I thank you for the opportunity to testify before you today about the opportunities in research regarding the general field of endoscopy, but also the difficulties the field of digestive diseases research is having as a result of budget reductions, both already accomplished, and proposed.

If one can gauge the future by recent years, certainly the field of endoscopy and the research enterprises it can and will assist show remarkable promise.

I would like to take a few moments to describe recent advances in endoscopy, and would like afterward to make several budgetary recommendations.

Gastrointestinal Endoscopy

Endoscopes use light-transmitting technology to illuminate internal organs and tissues in the body; the illuminated image is then sent back to the viewer through optical lenses or bundles of optical fibers. Fiberoptic endoscopy, for example, enables the physician to make a specific diagnosis of a gastrointestinal disease, often when xrays are not specific or normal. Specific sites of upper gastrointestinal bleeding can be identified. Polyps, the precursors of colon cancer, can be diagnosed and removed by this modality. The bile and pancreatic ducts are now accessible to these instruments and gallstones can be extracted without surgery. All of these endoscopic innovations have resulted in less surgery, shortened hospital stays and reduced time lost from work--not to mention reduced suffering and cost savings.

A new accessory for flexible endoscopes, a toposcopic catheter developed by NIH intramural scientists in the Biomedical Engineering and Instrumentation Branch (BEIB) is now undergoing clinical trials. It is used in conjunction with a drainage catheter that can be passed through the endoscope to drain fluids from the biliary and pancreatic ducts, and is extremely useful in patients with malignant obstructions. A three-way collaborative program between NIDDK, BEIB, and the Uniformed Health Services Medical School in Bethesda continues with results to be presented at the AGA meeting in San Francisco next month.

Another new adaptation, an endoscopic ultrasound imaging device, allows a physician to observe the full thickness of the intestinal wall, of importance in the diagnosis of Crohn's disease, a chronic disorder that involves the entire thickness of the bowel wall. This new device may well be useful in planning therapy for tumors of the stomach, esophagus, or colon.

Video technology in the field of endoscopy is moving forward rapidly. By connecting a recorder to a miniature endoscopic camera, a physician can obtain a high-resolution video image of the gastrointestinal tract and play back all or a portion of the recording for detailed analysis without involving the patient in additional examinations, and serves as an excellent record of the patient's stage of disease.

Lasers and other electrosurgical devices for use in endoscopy are improving rapidly, and not only allow endoscopic hemostasis of bleeding lesions, but also permits in many cases the destruction of cancers in patients who would not have been treated with surgery. However, one long-term need for the development of laser and fiberoptic technology is far afield from the laboratories of the National Institutes of Health and the academic and industrial scientists it supports. The need is in space. As the committee is probably aware, there is tremendous potential for the development of unique manufacturing systems and processes in a zero gravity environment. There are two elements of the zero gravity environment which could have a significant impact on fiberoptic technology. One of these is the ability to create homogeneous mixtures. On the earth's surface gravity tends to influence the heavier components of a mixture so that there may be an uneven distribution when the mixture solidifies. This state of non-homogeneity influences the efficiency of these solidified compositions altering electrical properties and longevity. A second area deals with the process of heating solid materials to form mixtures which then solidify after they cool. Whenever one performs this heating process on earth it must be performed in a crucible or vessel which can withstand the applied heat. Invariably, small amounts of the wall of the crucible dissolve and enter the molten material. This process introduces small amounts of impurities into the final product again reducing efficiency. Therefore, the society supports the concept of increased research in space on those manufacturing processes which can improve materials' purity and homogeneity.

As you can see, the use of the endoscope and its allied technologies can facilitate earlier and more accurate diagnosis and appropriate therapies, help avoid unnecessary surgical interventions, and also when used to remove colon polyps and common bile duct stones clearly reduces hospitalization time, the need for surgery, and the economic impact on the patient and insurance systems.

Increasingly, these improvements are proving to be beneficial to research programs, as they extend the fact-finding opportunities in such projects.

Appropriations for FY 1987 for Digestive Diseases Research

We would like to express our concerns, along with our colleagues in the field of digestive diseases research and the patient advocacy groups, about the serious problems which now exist in digestive diseases research funding.

First, we would like to indicate that the first year of Gramm-Rudman-Hollings, decreasing all program entities by 4.3%, in fact has reduced the fiscal year 1986 appropriations level to that of fiscal year 1985. This has caused serious problems in the funding of research grants, as well as serious problems for the continuous development of research manpower for the area of digestive diseases. You have heard many times of the negative effect caused by year by year variations in funding for the young people in our research fields, which cause them to be more and more uncertain about the opportunities for future careers.

Also, we are concerned about the funding of the Digestive Diseases Centers. As you have learned, these centers which have represented a major forward thrust for the digestive diseases community in the research area, were under-funded last year as cutbacks were made below the peer reviewed recommended level. Our concern is that if a second year of Gramm-Rudman-Hollings cuts (sequestrations) occurs, many of these centers will have to reduce their work force and research materials so significantly that any progress will be seriously hampered.

We are concerned about funding for the national Digestive Diseases Data System. As you know, Mr. Chairman, this data program has been mentioned in the past three years by appropriations bill reports, and we express our appreciation to you for that. However, it should also be understood that this program has never been funded despite your concerns. Additionally, last year in the Biomedical Research Amendments of 1986, the legislation which eventually passed, carried complete authorization for the Digestive Diseases Data System. Now that both authorization and appropriations committees have agreed to its need, we hope that you will see to its funding.

Also, Mr. Chairman, we support a level of $504 million for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and agree with the NIDDK Coalition on that amount for fiscal year 1987.

We also support the Ad Hoc Coalition for Biomedical Research's support of the NIH funding level of $6.07 billion for fiscal year 1987.

We are deeply grateful to you for that and for your support of all biomedical research.

APPROPRIATIONS HEARINGS FACTS SHEET FOR FY 1987

The American Society for Gastrointestinal Endoscopy recommends the following in terms of appropriations for digestive diseases research in FY 1987.

1. The continued funding of the Digestive Diseases Advisory Board, the Information and Education Clearinghouse for Digestive Diseases, and the beginning of funding for the authorized Digestive Diseases Data System.

   The latter is of considerable importance, as it would permit us for the first time to get a sense of the epidemiology of digestive diseases in the nation--this is particularly important for the improved treatment modalities utilizing endoscopy in its various forms.

2. The funding of the Digestive Diseases Centers across the nation. A new program, vigorously supported by appropriations only in the last several years, the centers program is already beginning to show advances in the field. However, in the last several years, cuts have been made to the agreed-upon levels of funding by the peer review system, and further cuts caused by a FY 1987 sequestration order following Gramm-Rudman-Hollings would cause severe cutbacks in the work being done there.

3. Increased attention should be paid to the very remarkable advances now occurring in the field of endoscopy, in terms of the contributions that can be made to research.

   The new technologies springing up in this field can have enormous consequences for research: for example, the toposcopic catheter is now undergoing clinical trials. It can be used in conjunction with a drainage catheter that can be passed through the endoscope to drain fluids from the biliary and pancreatic ducts, and is extremely useful in patients with malignant obstructions; another adaptation, an endoscopic ultrasound imaging device, allows physicians to observe the full thickness of the intestinal wall, and will aid in diagnosis of diseases such as Crohn's disease; and the field is being enhanced by video technology, which permits high-resolution video image-making and playback.

   Only appropriate levels of funding will permit research work to go forward in these areas.

4. Support is given to the NIDDK coalition's request for $504 million for this institute for FY 1987, and for the Ad Hoc Coalition on Biomedical Research' request of $6.07 billion for FY 1987.

STATEMENT OF E. DARRACOTT VAUGHAN, M.D., CHAIRMAN, DIVISION OF UROLOGY, NEW YORK HOSPITAL—CORNELL MEDICAL CENTER, ON BEHALF OF THE AMERICAN UROLOGICAL ASSOCIATION

Senator WEICKER. Our next witness is Dr. E. Darracott Vaughan, chairman of the department of urology, New York Hospital-Cornell Medical Center.

Dr. VAUGHAN. Thank you very much, Mr. Chairman. I appreciate the opportunity to return this year and discuss several aspects of urological funding with you. I would like to join the others in thanking you for your previous support.

I am the chairman of the research committee of the American Urological Association, and I also represent the American Association of Clinical Urology. I guess I primarily represent all of the senior men in our society who have benign prostatic hypotrophy, ladies with urinary tract infections, and children with genital anomalies more so than the societies whose name I am under.

I am also a member on urology of the Intersociety Council. Dr. Richard Freeman is our next speaker. With your permission, perhaps he could join me, and we could save some time.

Senator WEICKER. Why don't we do just that.

Dr. Freeman, why don't you join us. Welcome, it is nice to have you with us here.

Dr. VAUGHAN. I would like to spend my few moments here specifically discussing some of the action of this committee last year. As you know, in the House Report 99–289, your committee requested NIH to evaluate the proposal to establish the six kidney and urology centers, focusing on, among other things, obstructive and hereditary kidney disease of the urinary tract.

I understand that a report sent to Congress by NIDDK indicated that the major goals of the centers' program would be to focus on end-stage renal disease and benign prostatic hyperplasia.

I think the committee should note that end-stage renal disease, NBPH as it is called, has a combined annual cost in excess of $4 billion in the United States.

I think that you should also be aware, as far as benign prostatic hypotrophy is concerned, that we do not have any means at the present time for preventing this disease, and the entire effort is an operative effort in order to treat the disease once it occurs.

It is also apparent at the present time that benign prostatic hyperplasia causes obstruction of the urinary tract by means of both bulk, and its tone or tension. We somewhere on the brink of developing drugs to both reduce size and reduce tone.

Therefore, the NIDDK report concluded, and I quote:

> There is sufficient reason to believe that the proposed centers' program is scientifically feasible, will contribute positively to advances in research knowledge, and therapeutic approaches relative to end-stage renal disease and benign prostatic hyperplasia.

The NIH report, therefore, is supportive of the concept of kidney and urologic disease research centers.

Therefore, our first recommendation is that the six centers for renal and urologic research be funded with appropriate additional resources. Obviously, as urologists, we hope that the emphasis will be toward prostatic hyperplasia.

We also know that you have established an advisory board for the national kidney and urologic diseases, and we have heard previously today the excellent efforts of these advisory boards in such areas as arthritis and digestive diseases. We are very hopeful that funds will be continued for continuation of the kidney and urologic disease advisory board.

We realize that last year, language was placed for the institution of an interagency coordinating committee for coordination of kidney and urological research, and we hope that appropriate language will be moving forward to the funding of this committee.

PREPARED STATEMENT

We join with everyone else to talk with you today for support of the institute, and for NIH. I will turn the rest of the statement over to Dr. Freeman.

Senator WEICKER. Thank you, Dr. Vaughan.

[The statement follows:]

STATEMENT OF E. DARRACOTT VAUGHAN, JR.

I am E. Darracott Vaughan, Jr., Chairman of the Division of Urology at The New York Hospital-Cornell Medical Center and Chairman of the Research Committee of The American Urological Association. I am presenting this testimony on behalf of The American Urological Association whose membership of 6,200 represents the majority of American Urologists. I also represent The American Association of Clinical Urology and The Society of University Urologists.

Mr. Chairman, this has been an exciting year for the field of urology research. Space precludes extensive discussion of the many advances however let me review some of the most important. New technology including Extracorporeal Shock Wave Lithotripsy (ESWL) and ultrasonic methods for kidney stone destruction have virtually eliminated the need for the surgical removal of stones. Moreover new drugs are available to prevent stone recurrence.

Successful management of testicular and more recently bladder cancer with multidrug chemotherapy even in patients with extensive disease is now possible. Immunotherapy for kidney cancer has reached clinical application with promising early results. In terms of cancer detection, mandatory for identification of potentially curable early disease, ultrasound, magnetic resonance imaging, new tumor markers and flow cytometry have added dimensions to existing tests.

The advances in knowledge concerning the pathophysiology of penile erection has led the NIDDKD in conjunction with the NKF and urologic community to plan a workshop on impotence to be held at NIH in June.

Equally exciting advancements have been made in other urologic areas such as pediatric urology, neurourology, male infertility, incontinence, and urologic infectious disease.

Let me now move on to some specific areas of direct concern to the Appropriations Committee.

First, as you know, in House Report 99-289 the Committee on Appropriations requested an evaluation of the proposal to establish up to six Kidney-Urology Centers focusing, among other things, on obstructive and hereditary diseases of the urological system and kidney.

We understand that in the report sent to the Congress by the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases it was indicated in the Executive Summary that one of the major goals of a Centers program would be to focus on benign prostatic hyperplasia (BPH). You should know that kidney disease (end stage renal disease) and BPH have combined annual costs in excess of an estimated $4 billion, with those costs increasing steadily, according to that Executive Summary of the report made to the Congress.

Undoubtedly you know that current treatment on benign prostatic hyperplasia is only palliative and deals solely with complications of an already fully developed disease process.

We are pleased to understand that in regard to benign prostatic hyperplasia the National Institutes of Health, and the National Institute of Diabetes, and Digestive and Kidney Diseases in particular, believe that research advances regarding the potential causes of BPH, such as the isolation of testosterone receptors are now at hand. In addition scientists are in the process of isolating and purifying a prostatic growth factor which may cause BPH perhaps acting in concert with testosterone. It is also apparent that BPH causes obstruction to the urinary tract by means of both its bulk size and the tone or tension that it exerts around the urethra. Drugs are now being developed which should act to decrease the tone thus complementing potential drugs to decrease the bulk of the prostate.

Taken altogether these new approaches to the effective treatment of BPH are so exciting that NIDDKD sponsored a workshop last April gathering all the major scientists working in the area of BPH for discussion. As expected the workshop was highly productive and a number of new grant proposals have been submitted for potential funding.

Hence the NIADDKD report concluded: "Based on an evaluation of these considerations, there is sufficient reason to believe that the proposed centers program is scientifically feasible and that it would contribute positively to advances in research knowledge and therapeutic approaches relative to ESRD and BPH. The NIH is therefore supportive of the concept of kidney and urologic diseases research centers."

Therefore, Mr. Chairman, our first recommendation, resulting directly from the interest in the Congress in benign prostatic hyperplasia, is that these six centers for renal and urological research be funded with appropriate additional resources. Of course, as urologists, we have primary concerns that BPH centers be designated among those centers which should be funded to combat both ESRD and BPH.

In addition, we are pleased to note that you and nearly all the members of your Committee voted overwhelmingly to override the veto of the biomedical research authorization bill last year, which contained a number of new programs relating to urology. We are very hopeful that you will consider funding them this year.

First, a new advisory board has been established known as the National Kidney and Urologic Diseases Advisory Board. As you know, Mr. Chairman, there has been excellent progress made in other fields with the use of advisory boards (Diabetes, Arthritis, and Digestive Diseases Advisory Boards have been established years ago and have been funded by this Committee). We are very hopeful that you will establish funds, or at least insert bill report language in this legislation calling for the funding of a Kidney and Urologic Diseases Advisory Board.

Also, there is an Interagency Coordinating Committee established for Kidney, Urologic, and Hematologic Diseases in the new authorizing legislation. We are very pleased to say that the Urology Research Coordinating Committee established earlier by means of appropriations bill report language is now moving forward well. We look forward to the institution of this new Interagency Coordinating Committee to assure the best possible coordination of kidney and urology research.

There are two other mechanisms which have been established in the authorization legislation, including a Data System (Kidney and Urology Data System), and an Information Clearinghouse for Kidney and Urologic Diseases. We have studied with interest the superior impact that the Data Systems for Diabetes and Arthritis and Digestive Diseases have had in their areas of research, and understand that the Information Clearinghouses for all three disease categories have been very successful.

Mr. Chairman, because your Committee is so very influential in NIH matters, especially as to funding various programs, we would like you to know that the urology research community strongly supports continuing the integrity of the NIDDK, as it is now constituted. As you know, the biomedical research authorization bill passed last year required the Director of the NIH to review the existing research programs within our institute to see if they should remain, or be re-established in another institute.

We support, in the strongest terms, the continuation of the Kidney, Urology and Hematology cluster as it now exists. We are interdependent in research matters, and believe those portions of the kidney and hematology program now in this institute remain there.

In regard to our overall recommendations for funding, Mr. Chairman, we note that the proposed Administration budget for the NIH, for the NIDDK, and for all elements within NIDDK, is essentially below the fiscal year 1986 agreed upon levels.

We thank this Committee for not agreeing to go along with the President's proposed rescissions regarding the NIDDK, but wish you to know that the Gramm-Rudman-Hollings cuts of 4 1/2% from the institute's budget worked significant harm against many researchers, because the cuts came at a time when many grants were already made at a near to full funding at peer reviewed levels, and so subsequent grants coming up later in the fiscal year were harmed disproportionately.

We urge the Committee to provide a level of funding of $503 million for this institute (that assumes funds taken out for the new Arthritis, Musculoskeletal and Skin Institute). This level would provide a maintenance of effort at fiscal year 1986 levels.

We also recommend that the total appropriation to the National Institute of Health be 6.07 billion, in support of the Ad Hoc Group for Health Research funding.

Again, Mr. Chairman, we are deeply grateful to you for your interest in all of biomedical research, but especially your concern about research in urology.

I would be pleased to answer any questions you may have.

FOR APPROPRIATIONS TESTIMONY IN APRIL, 1986

The American Urological Association and the American Association of Clinical Urologists make the following recommendations to the Senate and House Subcommittees on Appropriations for Labor-HHS-Education programs:

1. We strongly support the NIH report to the Congress requested in House Report 99-289, accompanying the appropriations bill which called for an evaluation of the proposal to establish up to six Kidney-Urology Research Centers. Particularly we support the NIH conclusion that one of the major goals of such a centers program would be to focus on benign prostatic hyperplasia (BPH). This is an area ready for considerably more research, as the disease affects the majority of men over the age of 60.

2. We request appropriations to fund the new instrumentalities established by the recently passed biomedical research authorization legislation, including (all within the NIDDK):

    a. Kidney and Urology Advisory Committee,

    b. Kidney and Urology Data System,

    c. Kidney and Urology Education and Information Clearinghouse,

    d. Interagency Coordinating Committee for Kidney, Urology and Hematology Research.

3. We recommend support for the NIDDK Coalition's request for a budget of $504 million for the institute.

4. We recommend support for the Ad Hoc Committee for Biomedical Research proposed budget of $6.07 billion for the N.I.H.

5. We express concern that a device be instituted in some fashion which would assure the level of appropriations not be reduced by a second year of Gramm-Rudman-Hollings cuts.

    We recognize that the Adminsistration's proposed budget for FY 1987 is in fact lower than that originally provided in FY 1985, and suggest that in fact such a level would cause a decrease in research activity by more than 10%, given the costs of the biomedical research inflation levels.

STATEMENT OF RICHARD B. FREEMAN, M.D., PROFESSOR OF MEDICINE, UNIVERSITY OF ROCHESTER MEDICAL CENTER, THE INTERSOCIETY COUNCIL

Senator WEICKER. Dr. Freeman.

Dr. FREEMAN. Thank you, Mr. Chairman.

Again, I appreciate the privilege of being here. In the interest of time, I know you will understand that the amenities are here.

Dr. Vaughan really covered a great deal of what I was going to say. I simply would like to reiterate where I am coming from. I am a professor of medicine at the University of Rochester. I am the head of the urology unit there. I am representing the Intersociety Council for Research in Kidney and Urologic Diseases, of which the urology community is a part.

It is made up of nine organizations, with 15,000 members, and a lot of people. We contend that the only practical way to solve the dilemma of the end-stage renal disease program is to prevent people from ever arriving at that point, to where they require dialysis or transplant.

It, as you are well aware, is an expensive program to Medicare. We estimate that 22,000 new patients enter the end-stage renal disease program each year. Some estimates are as high as 55,000. It costs $2.5 to $3 billion a year.

We honestly feel, and we have studied this problem very carefully, that the scientific advances that were made possible through your very strong support, through R-1's and other awards, now make it possible to prevent a significant number of these people from ever getting end-stage renal disease requiring dialysis and transplant.

Hypertension accounts for a quarter of those patients. Hypertension can be controlled. Diabetes accounts for another quarter of those patients, and it can be controlled, not just through insulin, but it can be controlled through diet. Diet has positive effects on other kinds of kidney diseases, and so forth.

Therefore, we did recommend and we were pleased to see language in your report that support of the concept of an aggressive approach to institute protocols for treatment and for centers to gain more knowledge about how to prevent end- stage renal disease, which is due to both urologic problems and intrinsic diseases of the kidneys. We are very grateful for that.

Whether or not I ever live to see prevention totally occur, it is irrelevant. It is presumptious to ask now, in this fiscal climate, for additional funds. On the other hand, the advances that have been made scientifically are here, they are now, and they can be done.

We would be happy in any way to give documentation of this. Again, in the interest of time, will not go into all of the details of the different diseases that can cause end-stage renal disease.

I just might mention that the National Kidney Foundation is ready and able, and will support educational efforts through funding from the private sector for these centers and for the preventive programs.

Mr. Chairman, thank you very much. I appreciate the opportunity to present our views.

PREPARED STATEMENT

Senator WEICKER. I thank you both very much.

Let me say that any time is a good time to speak for the things that you are standing for, which I wish more people would do in this country. It would make it much easier for me.

Thank you very much.

Dr. VAUGHAN. Thank you.

[The statement follows:]

Statement of Richard B. Freeman

Thank you for providing me with the opportunity to comment on the appropriations for the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), for the fiscal year 1987. I am Richard B. Freeman, M.D., Professor, Department of Medicine, University of Rochester, New York, and Immediate Past President of the Renal Physicians Association. I appear before you today representing the Intersociety Council on Kidney and Urological Diseases, which is made up of virtually all groups active in research and the treatment of kidney and urinary tract disorders, with 15,000 physician and 50,000 lay members.

When we appeared before this subcommittee last year we recommended that you consider funding six multidisciplinary/multi-institutional kidney-urological centers. Your response in report language was encouraging. You noted:

> The science in kidney/urology diseases has advanced to levels that suggest the Institute (NIADDK) should give priority consideration to establishing centers of excellence in kidney disease, that emphasizes its relationship to nutrition, hypertension, cellular, diabetes mellitus, immunology and obstruction and hereditary diseases of the urological system.

We were further encouraged by the report the National Institutes of Health transmitted to the Congress in February, 1986, as a result of the directive in the Senate HHS Appropriations subcommittee report language.

> The NIH has evaluated the concept of establishing kidney and urological research centers within NIADDK (now NIDDK) and has concluded that research could be expected to benefit from a multidisciplinary and interdisciplinary approach provided by the centers research mechanism...

The report concluded:

> There is sufficient reason to believe that the proposed research centers program is scientifically feasible and that it would contribute positively to advances in research knowledge and therapeutic approaches relative to ESRD and BPH. The NIH is therefore supportive of the concept of kidney and urological diseases research centers, if resources were to be made available for this purpose.

We are aware of the tremendous cost of the Medicare End Stage Renal Disease Program. The outlays from federal trust funds are estimated between 2.5 and 3.0 billion dollars per year through 1990. We submit that the only practical way to reduce these outlays is to prevent new patients from advancing to the point where repetitive dialysis or transplantation is required to save their lives. Current conservative surveys estimate that there are 22,000 new patients that will require treatment each year. Some estimate the numbers could be as high as 55,000 new patients per year.

The Intersociety Council believes that with intensification of research as proposed in the centers the number of new patients entering the ESRD program can be reduced substantially (approximately 25%) over the next decade, resulting in a remarkable reduction in the number of patients requiring treatment. This would lead to dramatic cost savings for the federal government.

Mr. Chairman, it should be emphasized that last year was the first time the Kidney/Urology Community appeared before this subcommittee requesting directed funding for research initiatives. Indeed, the present body of knowledge has been developed through the traditional funding mechanisms of the National Institutes of Health. Until recently this has been appropriate for research needs and potential in the area of kidney and urological diseases. The time has arrived, however, for the science developed by individual investigators to be directed to a multidisciplinary and multi-institutional setting. We are now on the threshold of major advancements and this "state of the art" research in kidney and urinary tract diseases demands cooperation to assure its maximum benefits in human and economic terms.

The mission of each Research and Prevention center would be (1) to organize basic research aimed at factors which cause renal damage and develop approaches which prevent or reverse the deleterious effects, (2) to develop and execute appropriate clinical trials, and (3) to formalize prescriptions for treatments to reverse and prevent progression of renal disease.

The goal, which the Intersociety Council believes can be attained, is a profound reduction of the major causes of kidney diseases by the early 1990's.

You should also know that the National Kidney Foundation and its 50 affiliates has designed health promotion and education programs to complement the research aspect of the six center concept. This professional and public education program will provide the demonstration component for the Research and Prevention Centers and will be funded from the private sector.

The benefits-to-costs ratio - in terms of both dollars and the human condition - resulting from implementation of these six centers will be immense. I therefore respectfully urge you to provide the funding for these six Research and Prevention Centers.

Mr. Chairman, The Intersociety Council also urges the Committee to provide a level of support in fiscal year 1987, to assure 6,219 competing awards for the NIH. This would assure full support for 648 grants at the NIDDK.

Thank you.

STATEMENT OF EDWARD D. BRANSOME, M.D., BOARD OF DIRECTORS, AMERICAN DIABETES ASSOCIATION

Senator WEICKER. The next witness is Dr. Edward Bransome, member of the board of directors of the American Diabetes Association.

Dr. BRANSOME. Senator, I am most pleased to be able to appear on behalf of the American Diabetes Association. I am a member of the board of directors, and the organization's government relations committee, and will be the chairman of that committee in June.

Perhaps my greater distinction is that I missed being a classmate of yours at Yale by 1 year.

Senator WEICKER. Which class were you at Yale?

Dr. BRANSOME. 1954.

Senator WEICKER. He is younger than I.

Dr. BRANSOME. I should also say what else I am. I am a physician, professor of medicine at the Medical College of Georgia. I take care of the patients with diabetes. I have spent part of my time doing research.

I have submitted written testimony, which I will not attempt to repeat. I must say that some of the testimony before this was certainly eloquent. Suffice it to say that the Diabetes Association strongly supports and recommends the $6.1 billion figure for the NIH as a whole, and the approximately $503 million for NIDDK.

We also commend and express our gratitude for your previous and current efforts to maintain an adequate level of NIH funding. I also would point out that the President's budget is also severely threatening another effort, not in the NIH, but the Centers for Disease Control, the Diabetes Control Program, which has been, in its 6 years of existence, one of the most effective methods of expending the Federal dollars that I, at least, have ever seen.

The CDC Diabetes Control Program for the last 2 fiscal years, including the current one, has been funded at $7.5 million. Some $5 million of this amount is allocated to programs in soon to be, we hope, 26 States around the country to prevent complications of diabetes. In other words, an effort to translate research findings into practice.

The President's budget removes these $5 million. Diabetes as a whole is a costly disease, involving 11 million people, according to the National Diabetes Data Group as of several years ago, at least a $14 billion medical expenditure. Many of the NIH initiatives, apart from the CDC, not only are important and praiseworthy, in our estimation, but also have the potential of being extremely cost effective, if not immediately, eventually.

One which will be cut back at the fiscal year 1987 President's budget levels is the diabetes control and complications trial, which is now through its feasibility stage, which will involve over 1,400 subjects, and will attempt to address and answer the question of whether tight control of diabetes will prevent the devastating complications of diabetes.

As I know you know, and as we just heard, 25 percent of end-stage renal disease is attributable to diabetes. It is the leading cause of blindness in adults. It accounts for at least one-half of 40,000 lower limb amputations per year. It is an extremely significant factor in mortality from cardiovascular disease.

Last, as I finish, we are also concerned about the cutback in training funds for research trainees, and also minority health care professional training programs and student aid. The diabetes affects the general population of the United States in the ways that I have described, but minority populations, particularly the blacks who have 160 percent of the rate of diabetes of white Americans, Hispanic Americans, twice the rate of diabetes, and American Indians, with some tribes so heavily affected by diabetes that over 50 percent of all Indians in these tribes over the age of 35 may have diabetes and all of its attendant complications.

We regard those cutbacks as threatening the health care delivery of some of the advances in research that we already have available to us.

Thank you, sir.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. I appreciate your testimony. Your statement in its entirety will be placed in the record.

[The statement follows:]

STATEMENT OF EDWARD D. BRANSOME

Introduction

Mr. Chairman: I am Edward Bransome, a member of the Board of Directors of the American Diabetes Association (ADA) and the Chairman designate of the Government Relations Committee of the American Diabetes Association. The American Diabetes Association has 58 affiliated associations and more than 200,000 lay and professional members. The ADA is very interested in and concerned about the budgets under your Subcommittee's jurisdiction dealing with biomedical research, manpower training and health care services. These programs are very important to the 11 million individuals with diabetes and its complications. As you know, these complications affect the heart, kidneys, eyes and the nervous system. Diabetes is the fifth leading cause of death by disease and is a major factor in disability in this country. It is also the leading cause of new blindness in adults. The economic burden of diabetes is approximately $14 billion annually.

Thanks to you Mr. Chairman and your Subcommittee, we have made great strides in dealing with the problem of diabetes, particularly through programs which receive appropriations from this Subcommittee. For example, approximately $190 million was budgeted and expended in Fiscal Year 1985 by NIH for research related to diabetes. The Centers for Disease Control (CDC) support a $7.5 million program to prevent the complications of diabetes. In addition, major health service programs are significant for the care of those with diabetes; the Maternal and Child Health Program is particularly important because of the services it provides to women with diabetes and their children.

FY 1987 Budget Proposals

National Institutes of Health

Programs of the National Institutes of Health (NIH) have produced many important developments in recent years regarding diabetes. Those programs already have produced or will produce major savings in health care payments and disability payments. (1) The development of laser therapy for the treatment of diabetic retinopathy has already saved in Medicaid and welfare payments three times the research funds spent for the development of that treatment. (2) The Diabetes Control and Complications Trial (DCCT) has passed through its feasibility stage and is now at full operation. The objective of the DCCT is to establish whether strict control of blood glucose reduces the incidence of complications arising from diabetes. Approximately 1200 individuals will be studied during the course of this clinical trial. The potential savings from knowledge gained about the effectiveness of strict control in treating Type I diabetes and the prevention of eye disease and other complications is conservatively estimated at $350 million annually by the NIH. The savings are likely to be more than that since such knowledge would be applicable to the treatment of Type II cases also. (3) Research related to transplantation of pancreatic islet cells has been expanded in recent years. Currently, two centers are doing clinical studies on this matter and some of the results are quite positive. (4) Research supported by the National Institute of Child Health and Human Development has enabled progress to be made in the treatment of pregnant women who are afflicted with diabetes and has resulted in reduced rates of disabling conditions among the children of such women. The health care and disability payments for the disabled children who have been born of mothers with diabetes are extraordinarily high. While we have not calculated the savings from such advances we know they are substantial.

The President's budget for the National Institutes of Health and particularly for the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) will set back this progress enormously. Let me just mention a few of the research activities that will not be undertaken in Fiscal Year 1987 under the President's budget because of its extremely low dollar recommendation. (1) There is at least one approved but unfunded diabetes and endocrinology research center that will not be funded. The number of such centers has remained stable for many years. The program has been very successful in stimulating new developments in research and translating that research into practice. (2) A very important study with enormous potential for cost effectiveness, dealing with early intervention in the treatment of those with diabetes who have kidney disease, will not be supported. Approximately 30% of all Medicare recipients who are undergoing kidney treatment and dialysis have diabetes. (3) Equipment and instruments for research are antiquated and we lag behind in their quality. A major program to improve the equipment and instruments used by the scientists who deal with diabetes and endocrinology will not be supported. (4) An initiative to obtain and distribute human tissue for use in biomedical research and islet cell and pancreatic transplantation will not be undertaken. (5) Finally, the Diabetes Institute had intended to undertake a major initiative with regard to health care for minority populations with diabetes and will not be able to do so if the President's budget is adopted.

If the President's budget were adopted, the Diabetes Institute will only be able to fund less than 25% of all approved research applications, the lowest rate of any Institute. For NIH as a whole, as you know, the numbers of research grants will be reduced by 1,000 and the numbers of trainees to be supported in FY 1987 will be 1,500 fewer than in FY 1985. Based on NIH estimates, the minimum acceptable award rate for approved research project grants is 50 percent. If that award rate is not maintained, the resulting reduction in the numbers of research grants and trainees will set back science generally and will discourage young scientists from careers in biomedical and behavioral science. There will also be a loss to science of many existing biomedical scientists who cannot get support for their research.

The American Diabetes Association Proposal

We, along with many other groups, recommend a budget for the NIH which would be approximately $6.1 billion in FY 1987. Such a budget would support the same level of research activity in FY 1987 as undertaken in the current year if the FY 1986 appropriation had been implemented, including about 6100 new grants at full funding. It would provide for the full funding at peer review recommended levels of research grants for all programs. Training and career development programs could be adequately supported at slightly above current service levels.

We also urge the Subcommittee to expand NIH funding of the biomedical research support program for minorities.

With respect to the NIDDK, we recommend a budget of approximately $500 million. That budget would enable the Institute to fund about 637 new grants and to undertake those initiatives which I have referred to before. The budget would enable full operation during Fiscal Year 1987 of the diabetes complications clinical trial. Islet cell and pancreatic transplantation research would also be adequately supported.

We think this level of funding is absolutely essential in order to simply continue current progress and we would urge that the Subcommittee provide the recommended funds for the National Institutes of Health and the Diabetes Institute.

We believe that our proposal would provide NIH with a balanced program of research grants, centers, training, clinical trials, and intramural research. We urge that NIH have sufficient flexibility to support such program balance whatever the level of appropriation provided.

2. Centers for Disease Control

The Centers for Disease Control budget currently supports the Diabetes Control Program (DCP). That program is supported at $7.5 million of which $5 million is provided to state health departments for program activity. It should be noted that the States with DCP programs often provide substantial state investment in the program. The federal money induces that investment. The Subcommittee has assisted in protecting this program from elimination in prior years. The program has been very cost effective. The DCP supports 20 State programs; an additional 10 one-year programs were started last year. The program has recently focused upon supporting preventive services related to specific complications of diabetes such as eye disease or pregnancies with complications of women with diabetes. Savings produced by this program are substantial and result from reduced hospitalization, reduced surgery rates and reductions in morbidity and mortality. This is an example of a program in which research results are cost-effectively translated into practice. Examples of such programs which have similar cost savings are South Carolina, Maine and Kentucky.

The President's budget for FY 1987 proposes to eliminate the $5 million program of support to State health departments and retain only the in-house staffing aspect of the program. This proposal is similar to ones made in the FY 1985 and FY 1986 budgets. We urge the Subcommittee to at least continue the Diabetes Control Program at its current level of $7.5 million. We would also urge that the Subcommittee support the CDC approach of targeting programs on specific complications and urge the CDC to focus the program on those minority populations where the prevalence of diabetes is so great. Language in the Committee Report to this effect would be very helpful.

3. Health Manpower Training

The President's budget recommends the elimination of support for most all health manpower training. One such program of great importance to our constituency is the training of health professionals to serve minority populations. As noted in the Secretary's Task Force Report on Black and Minority Health, minority populations have excessively high rates of diabetes and the complications of that disease fall much more heavily on those groups. We also do not have sufficient professionals serving the minority population. In order to assure adequate and up to date health care for those populations, we believe that health manpower training, particularly for students from disadvantaged backgrounds, is essential. We need to train more health professionals who will provide service to minority populations. The President's budget for FY 1987 would eliminate the program of assistance to disadvantaged students. We strongly recommend that the Program be expanded in FY 1987 over the FY 1986 level. This expansion would be one way to implement the objectives of the Secretary's Task Force Report on Black and Minority Health. We would urge that the Committee suggest to the Department that initial emphasis in some of its curriculum and special projects activity be placed upon the training of minority health professionals in the diagnosis and treatment of diabetes and related disorders.

Mr. Chairman, we are making a number of of other recommendations about many appropriations programs, some of which are not in the jurisdiction of this Subcommittee. We would like to submit that material for the record. I would be very happy to answer questions about diabetes and the programs which we hope will enable us to find a cure or to better treat those with diabetes.

STATEMENT OF EILEEN GELICK, PRESIDENT, JUVENILE DIABETES FOUNDATION

ACCOMPANIED BY JOSEPH FISCHBEIN, PRESIDENT OF THE BOARD, JUVENILE DIABETES FOUNDATION

Senator WEICKER. The next witness is Eileen Gelick, president of the Juvenile Diabetes Association.

Mr. FISCHBEIN. We are going to testify together. You don't have me down there, but I am Joseph Fischbein, and I am the president of the board of the Juvenile Diabetes Foundation [JDF]. I live in New Haven. I am also the father of an 18-year-old who has had diabetes since he was 1 year of age.

I would like to just tell you something about where we think we are today. Eileen Gelick, who is the president of the foundation, can tell you about some findings that have been made at this time.

As I mentioned, my son is 18, and he has had diabetes for 17 years. As I know you know, after 15 to 20 years of having diabetes, complications develop, so I am sure you can appreciate my sense of urgency personally.

In 1984, JDF testified that we were on a countdown toward the cure of the disease. Today, as the countdown draws closer toward its ultimate objective, we face a turning point in the in the battle against insulin-dependent diabetes. We can either continue on the path toward a cure, or we can turn away from the important goal of curing diabetes, and other major health concerns, because of budgetary concerns.

Although Congress has been faced with difficult budgetary decisions over the past several years, the members of this committee have repeatedly stood their ground, protecting the biomedical research effort, which is the envy of the world. We can now point to major successes in the treatment of this Nation's diabetic, and we have a reasonable reason for being optimistic about a cure, and also prevention for this insidious disease.

Researchers have already successfully transplanted clusters of insulin-producing beta cells from one animal species to another. Scientists have demonstrated that beta cells from healthy rats transplanted into diabetic mice actually reverse the diabetes in mice. Now clinical trials in pancreatic islet transplantation have been finally initiated on human subjects to test whether this procedure can indeed cure diabetes.

In light of the progress that has been made in diabetes, and other biomedical research, the administration's request for cutbacks in NIH funding is both unconscionable and shortsighted. As allocated on the table attached to our testimony, we support a 2.4 increase in NIH's budget in fiscal year 1987, and the $6.1 billion, a figure supported by 100 major health organizations.

The current services budget has enabled the Diabetes Institute, NIDDK, to support several initiatives, which could not be funded under the administration's budget proposal, and to expand the multicenters, and the transplantation initiative, and expansion of support for the procurement and the distribution of human tissues for research, and the reinstatement of the kidney and urology components of the diabetes control and complications trial that have been taken out.

While we are happy to report that there are many exciting diabetes initiatives being supported throughout NIH, there are a few examples of totally inadequate commitment to diabetes research, most notably within the National Institute of Neurological and Communicative Disorders and Stroke. We are extremely disturbed by NINCDS's continued lack of interest in supporting research in the area of diabetic neuropathy, a devastating complication of diabetes.

The Institute's lack of responsiveness is exemplified by its withdrawal from the diabetes control and complications trial, and its failure to establish research or training initiatives designed to promote interest in the area. We respectfully recommend that $479 million be appropriated to NINCDS and that the Institute be directed to expand its research into the neurological complications of diabetes.

We hope that in committee report language, the committee will instruct the Institute to assume its proper place with respect to diabetes research.

Mr. Chairman, we have come a long way in diabetes research. While estimates place the social and health care costs of diabetes as high as $15 billion, the Congress can make the sound investment choice to increase funding for the Federal diabetes research effort. We want nothing more than to put JDF out of business, and the Federal diabetes research initiative as well, but the bottom line is: Have our children been cured?

I would like to ask Ms. Gelick if she would just spend a moment telling you about one or two of the benchmark advances that have occurred as a result of support from this committee.

Senator WEICKER. Eileen, I would be happy to hear your testimony, but we are running 1½ hours late, and we still have two witnesses to follow.

Ms. GELICK. I appreciate the opportunity to travel around the country and talk to many people. This has given me the opportunity to see how your courage has really been reflected in the lives of people.

Briefly, I would say, I met with one member, who is in his thirties. He has two small children. He has been a diabetic for 20 years. I met him 1 year ago, and he was almost completely blind. He was angry. He was aggressive. He was desperate. He was without hope.

I met him again 2 weeks ago, and that man had a total personality change because of the use of a retrectemy in one eye, which was able to restore his vision to 20/40, because of laser treatment in the other eye, he was able to have almost normal vision in the other eye.

We now have a man who can lead a normal life as a father and as a husband, as a productive citizen, without being a burden on society.

My second meeting was with someone who is 34 years old. He was diabetic for only 7 years. I met with him and his doctor, who is a researcher working on inhibitors. He has severe neuropathy, and he was going blind. He was impotent. He was told he needed one leg amputated, and he was also told that he would be dead in 2 years.

After participation in the research program, it was like a miracle. He had complete reversal on his vision, and had almost no neuropathy pain. He did not need to have his leg amputated, and the prognosis was life.

I will respectfully say that we know the research is good, we know that very well, but we don't yet have all of the answers. We know that it is our only hope. We were told by the founders of our country that we had certain unalienable rights, and one of those was life. Some 200 years later, that there are some very complex decisions to be made, but we think that it is pretty straightforward, it simply is a choice between life and death.

PREPARED STATEMENTS

I would like to thank you for your concern, but most of all I would like to thank you for actions on behalf of all of us. I would like to pledge our support in anything that we can do.

Thank you.

Senator WEICKER. Thank you. Your statement will be included in the record at this point along with other statements submitted for the record on appropriations for the National Institute of Diabetes, Digestive and Kidney Diseases [NIDDK].

[The statements follow:]

STATEMENT OF EILEEN GELICK

Summary of Recommendations:

The Juvenile Diabetes Foundation International recommends that, for FY 1987, the National Institutes of Health be appropriated $6.079 billion (a 10.4% increase over the FY 1986 funding level). The National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) should be appropriated $503.7 million; the National Heart, Lung, and Blood Institute (NHLBI) - $950 million; the National Institute of Child Health and Human Development (NICHD) - $356 million; the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) - $479 million; the National Institute of Allergy and Infectious Diseases (NIAID) - $424 million; and the Division of Research Resources (DRR) - $338 million.

We also recommend that $7.5 million be appropriated for the Centers for Disease Control's State Diabetes Control Projects and that the Indian Health Services be appropriated $2.4 million to operate the Model Diabetes Care Program.

DIABETES RESEARCH: AT A TURNING POINT

The Juvenile Diabetes Foundation International (JDFI) appreciates this opportunity to present its views regarding FY 1987 appropriations for the National Institutes of Health (NIH) and other federal diabetes programs. JDFI is an international voluntary health organization of over 160 chapters throughout the United States and the world dedicated to furthering research in diabetes and improving the quality of life of the diabetic.

In 1984 JDFI testified of our "countdown" toward a cure for diabetes. Today, as the countdown draws closer toward its ultimate objective, we face a turning point in the battle against insulin-dependent diabetes. We can either take the path toward a cure for this dreaded disease or we can capitulate to the budgetary red-liners at the Office of Management and Budget (OMB), turning away from the important goal of curing diabetes. Such a retreat would serve as a victory for those who seek immediate savings in federal spending.

Although Congress has been faced with difficult budgetary decisions over the past several years, the members of this Committee have repeatedly stood their ground, protecting a biomedical research effort which is the envy of the world. Today, JDFI submits its appropriations request in the face of the gravest threat ever; the specter of the Gramm-Rudman balanced budget legislation haunts us all. The threat of across-the-board budget cuts, a policy approach which JDFI and many on this Committee opposed from the very outset, is ominous. But the effort to attain the budget targets embodied within the legislation, so as to avoid triggering automatic reductions, may be equally onerous.

Basic and clinical biomedical research holds the promise of a cure for diabetes and countless other diseases that kill and cripple millions of Americans annually, exacting a monumental toll in human suffering. Moreover, the costs associated with health care treatment and lost wages and productivity soar into the billions of dollars. Dedication of modest resources to finance science is an intelligent investment in the future health of the nation. But most importantly such a commitment reflects the compassion of those who establish public policy for individuals in the shadows of life -- the young and the sick.

Moreover, diabetes research is cost-effective. For example, an annual savings of $454 million in the national cost of care for the blind can be realized through the use of laser therapy in advanced cases of diabetic retinopathy. Multiple similar examples exisit. At the same time, on the other side of the equation, the federal government spends over $400 million per year supporting diabetics on dialysis -- two times the NIH allocation for diabetes research.

Thus, research not only improves the quality of life of the diabetic, it ultimately promotes containment of health care costs.

THE FEDERAL DIABETES PROGRAM

Over the past dozen years, the federal diabetes program has come into its own. We now have the momentum to develop a diabetes preventive, to mitigate many of the disease's devastating complications, and, hopefully, to attain a cure. Indeed, the mechanism for continuing the federal onslaught on diabetes is securely in place: research is conducted in virtually every NIH Institute. There are seven diabetes research and training centers and four diabetes endocrinology research centers in operation. The Diabetes Data Group and the Diabetes Information Clearinghouse are effectively performing the functions mandated by Congress. The National Diabetes Advisory Board (NDAB), a body of government officials, health care professionals, and consumer-advocates, including a number of JDFI members, provides a coordinated focus for the plethora of federal diabetes-related activities. In one of its functions, the NDAB periodically revises our "blueprint" for a cure, the Long Range Plan to Combat Diabetes.

THE ADVANCES IN DIABETES RESEARCH

Today we are at a turning point because of the efforts of this Committee over the past decade. The investment you have made has paid off in enormous dividends. We can now point to major successes in the treatment of this Nation's diabetics. Moreover, we now have a reasonable basis for being optimistic about a cure and the prevention of this insidious disorder. Consider, for example:

- Researchers have already successfully transplanted clusters of insulin-producing beta cells from one animal species to another. Scientists have demonstrated that beta cells from healthy rats transplanted into diabetic mice actually reverse the diabetes in mice. Now, clinical trials in pancreatic islet transplantation have been finally initiated on human subjects to test whether this procedure can, indeed "cure" diabetes.

- NIH-sponsored research has responded to the need for a better method to deliver insulin. Several alternatives, at various experimental stages, have been produced by this research: an insulin nasal spray, an insulin inhalant, micro-electronic computerized insulin pumps, and transplantation of insulin-producing beta cells.

- Diabetic blindness is devastating and widespread; moreover, it is perhaps the most feared diabetes-related complication. Now, due to the research sponsored at NIH, laser technology and new surgical procedures have reduced the incidence of new blindness among diabetics by as much as 60 percent.

- Diabetic pregnancies used to entail a much higher than normal risk of fetal death or congenital malformation. Now, through NIH sponsored research,we know that when blood sugars are normalized through tight control, a diabetic woman's risk of infant mortality falls to approximately the same level as the non-diabetic population.

- Recent NIH research is focusing on the action of an enzyme, aldose reductase which converts glucose into a form of alcohol called sorbitol. Concentration of sorbitol in the system, a condition which is common in diabetes, causes cell deterioration. Thus, in turn, results in loss of sight, kidney and nerve damage. Understanding this process has enabled scientists to develop drugs which block the enzyme and thus prevent the accumulation of sorbitol. These drugs are now being tested with positive results to retard damage to nerve tissue, as well as to resolve kidney and eye complications.

THE SCOPE OF DIABETES

Despite the cause for optimism in diabetes research, the specter of diabetes and its devastating complications defines the alternative path we approach at this turning point. Diabetes is the third leading cause of death in the United States; the leading cause of new blindness; the cause of 50% of foot and leg amputations among adults; the cause of severe neurological disorders; the cause of a disproportionately high rate of infant mortality, congenital malformations, respiratory distress, prematurity, and other serious medical problems; a major risk factor for cardiovascular disease; and the cause of 20% to 25% of kidney failure. Indeed, experts estimate that $15 million is sapped from the American economy per year in both the direct and indirect costs of this disease.

THE ADMINISTRATION'S FY 1987 BUDGET

Against this backdrop looms the Administration's proposed budget for FY 1987: a bleak and desolate path of retreat and retrenchment from a responsible health care policy. The elements of the President's biomedical research policy include proposed funding reductions in FY 1987, ill-advised "micromanagement" of the scientific programs at NIH, OMB-proposed reductions in direct and indirect costs of research grants and, rejection of major new initiatives in diabetes research and other areas of overwhelming scientific opportunity.

For FY 1987 the President recommends cutting NIH funding to $4.9 billion. This represents a 5% reduction below the actual FY 1986 level of funding and an unconscionable 10% reduction below the FY 1986 level as appropriated by Congress. These cuts would be achieved through paring back the number of new research awards to 5,104. NIH would face a significant reduction in numbers of research centers. Indirect costs would be reduced by $85 million through imposition of a cap.

This level of support would further: limit funding for high quality research by substantially reducing the payline for new and competing research grants; provide dollars for only 27% of approved research grants; reduce the number of approved clinical trials thereby restricting the migration of new therapies "from bench to bedside"; exacerbate the deterioration of the physical plants and animal laboratories at institutions across the nation; freeze the number of research trainees despite a critical shortage of young clinical investigators; and reduce the number of full-time equivalent NIH employees.

We have spoken of the "investment" in biomedical research, and of the importance of "research and development" in every enterprise, private sector or governmental. These devastating reductions in NIH funding are all the more intolerable because the Administration has proposed a government-wide R&D average increase of approximately 17% which would augment the number of defense-related research scientists from 5,000 to 18,000. It is insidiously ironic that, concurrently, we will lose many of the bright young clinical investigators who may cure diabetes, heart disease, cancer, and other major health problems in the years ahead.

We are also concerned with OMB's increased involvement in the management of NIH affairs. As of August, 1985, OMB instituted a new mechanism for apportioning funds within NIH thereby expanding the control of bureaucrats over the number and size of awards and the allocation of funds among program mechanisms, such as clinical trials, centers, population studies, research career and training awards and developmental contracts. It is imperative that Institute Directors and NIH Advisory Councils be afforded ample flexibility to identify and provide appropriate support for initiatives embodying scientific merit.

JDFI FUNDING RECOMMENDATIONS FOR NIH

Today we face a major choice. As we approach the major turning point in biomedical research into diabetes, Juvenile Diabetes Foundation International recommends that Congress appropriate $6.079 billion for NIH in FY 1987. This request, as allocated on the table of recommendations appended to this testimony, represents a 10.4% increase in the NIH budget.

For the most part, our proposed budget would simply maintain current services at the levels provided by Congress in the FY 1986 appropriations bill. New and competing research grants would be funded at a priority score of about 165-170 with 33% of approved applications receiving support. Funding at these levels would allow for modest growth in research career awards and funds sufficient to raise the current level of research trainees to that recommended by the National Academy of Sciences (NAS). This proposal permits needed upgrading of primate centers and research laboratories. A funding level of $6 billion provides additional monies for General Clinical Research Centers (GCRCs) to facilitate the conduct of research projects and trials. Finally, at this level of support a slight increase in the number of research centers is insured.

National Institute Of Diabetes, Digestive and Kidney Diseases (NIDDK)

Within this increase, we recommend that, for FY 1987, Congress specifically allocate $503 million to the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), the cornerstone of the federal diabetes research effort. Under the Administration's budget request fully 11% fewer new research grants would be funded in FY 1987 than were supported in FY 1986.

A $503 million budget for NIDDK would restore cutbacks in research grants, traineeships, career awards, and intramural programs. Full indirect and direct costs would be paid for 637 new and competing research grants, thus maintaining the current fiscal year's level of support. Our recommended budget would permit the funding of about 33% of all approved research grants, a rate consistent with recent years' appropriations. It is also necessary to provide ample funds to pay for grants at study section-approved levels. Enactment of the Administration's budget would result in further downward negotiations in grant payments, thereby jeopardizing the scientific integrity of these projects. Moreover, any reductions in direct and indirect funding should reflect an overall agreement between Congress, the research community, and NIH.

Under the Administration's budget, many major diabetes initiatives would be eschewed. At our proposed funding level of $503 million, the Institute would be able to reconsider supporting the following initiatives: a new transplantation initiative; an expansion of support for the procurement and distribution of tissue for research; an increase in the number of diabetes/endocrinology centers; and reinstatement of nephrology and neurological components within the Diabetes Control and Complications Trial.

The NIH Reauthorization legislation, adopted in 1985 authorized the creation of an arthritis Institute out of the existing National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases (NIADDK). The cost of establishing the new Arthritis institute has been set at $3.5 million. Thirty-six new staff positions would be required. These additional resources have not yet been provided. The diabetes program of NIDDK will be severely hampered and the intent of Congress will be thwarted if the necessary resources are not immediately forthcoming. Under no circumstances should the funds allocable to the residual institute for research or administrative programs be diverted to support the new NIAMS.

National Heart, Lung, And Blood Institute (NHLBI)

Under the superb leadership of Dr. Claude Lenfant, the NHLBI has continued to offer enormous support for diabetes research. The high level of visability for diabetes within NHLBI reflects the fact that diabetes is one of the four major risk factors of cardiovascular disease, including stroke, arteriosclerosis, and coronary heart disease. JDFI believes that $950 million should be appropriated to NHLBI so that it can expand its diabetes research program and maintain an effective and programmatically balanced heart, lung, and blood initiative.

National Eye Institute (NEI)

As discussed above, diabetes is the leading cause of new blindness in the United States; its costs in terms of health dollars, lost productivity, and human pain and suffering are momentous. The National Diabetes Advisory Board has identified several priority areas for ocular research which can continue to be implemented if Congress appropriates $216 million to the National Eye Institute.

National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

While there are exciting diabetes initiatives being supported throughout NIH, there are a few examples of totally inadequate commitment to diabetes research, most notably, the National Institute of Neurological and Communicative Disorders and Stroke. We are disturbed by NINCDS' continued lack of interest in supporting research in the area of diabetic neuropathy, a devastating complication of diabetes. The Institute's lack of responsiveness is exemplified by its withdrawal from the Diabetes Control and Complications Trial (DCT) and its failure to establish research or training initiatives designed to promote interest in the area. We respectfully recommend that $479 million be appropriated to NINCDS and that the Institute be directed to expand its research into the neurological complications of diabetes.

CENTERS FOR DISEASE CONTROL (CDC)

CDC has spearheaded a number of very significant programs designed to implement the Long Range Plan to Combat Diabetes. Despite this success story the President's budget would eliminate funding for this program altogether. JDFI recommends that Congress appropriate $7.5 million for CDC's National Diabetes Control Program in FY 1987.

INDIAN HEALTH SERVICE

Diabetes is a critical health problem among American Indians, affecting almost 50% of adults in some tribes. Several years ago, Congress authorized a Model Diabetes Health Care Program to develop and evaluate effective and culturally acceptable methods to reduce the severity of the disease. Legislation has recently been introduced to expand this program. Consistent with this direction and with the need to accelerate the transfer of effective diabetes control strategies to other units within the IHS service population, JDFI recommends that Congress provide $2.4 million in FY 1987 for this program.

CONCLUSION

We have come a long way in diabetes research -- over a dozen research breakthroughs in just a few years. While estimates place the social and health care costs of diabetes as high as $15 billion, Congress can make the sound investment choice to increase funding for the federal diabetes research effort. We want nothing more than to put JDFI out of business, and the federal diabetes research initiative as well. But the bottom line is: Have our children been cured?

We pray that the Members of this Committee, will maintain their vision, ignoring what may be politically expedient. OUr hope is that you will continue to do what you know in your hearts was right. In this way we will achieve our goal — biomedical reserach will continue to thrive and the high road will be taken.

JUVENILE DIABETES FOUNDATION: FY 1986 APPROPRIATIONS RECOMMENDATIONS[1]
in millions of $

NATIONAL INSTITUTES OF HEALTH	FY 1986[2/] Approp.	Diabetes Dollars In FY 1986	AFTER GRAMM-RUDMAN FY 1986 CUT[3/]	ADMIN. FY 1987	JDF Recommendation	Diabetes Dollars Under JDF Rec.
National Institute of Diabetes, Digestive and Kidney Diseases	456.1	(109.5)	436.1	419.0	503.7	(124.0)
National Heart, Lung, and Blood Institute	859.9	(20.5)	811.5	785.7	949.6	(24.0)
National Eye Institute	195.2	(23.2)	186.6	179.2	215.6	(26.0)
National Institute of Child Health and Human Development	322.3	(11.9)	308.2	309.1	355.9	(13.0)
National Institute of Neurological and Communicative Disorders and Stroke	433.4	(4.7)	413.0	399.4	478.6	(6.5)
National Institute of Allergy and Infectious Diseases	384.0	(5.9)	341.4	330.6	424.1	(8.0)
National Institute of Aging	157.8	(2.2)	150.9	145.8	174.3	(2.2)
National Institute of Dental Research	103.4	(4.9)	98.2	96.5	114.2	(5.0)
National Institute of General Medical Sciences	516.0	(1.1)	493.6	471.5	569.7	(1.2)
National Institute of Environmental Health Sciences	197.5	(.3)	188.9	188.0	218.1	(.5)
National Institute of Arthritis, Muscoloskeletal and Skin Diseases	116.5		111.3	106.7	128.1	
National Cancer Institute	1,256.5		1,174.3	1,158.1	1,387.6	
Division of Research Resources	305.7	(15.5)	290.8	234.2	337.6	(17.0)
National Library of Medicine	57.8		55.3	56.4	63.8	
John E. Fogarty International Center	11.6		10.9	11.3	12.8	
Office of the Director	117.0		45.0	36.7	129.2	
Buildings and Facilities	14.9		14.3	8.0	16.5	
TOTAL NIH	5,505.2	(199.7)	5,130.3	4,936.2	6,079.4	(227.4)

[1] Figures in columns may not foot because of rounding.
[2] FY 1986 Appropriations Figures Include FY 1985 Carryover.
[3] All reductions reflect across-the-board cut of 4.3 percent.

Centers for Disease Control Diabetes Control Project	5.0	(5.0)	4.8	0.0	7.5	(7.5)
Indian Health Service Model Diabetes Care Program	1.9	(1.9)	1.8	1.8	2.4	(2.4)

STATEMENT OF WILLIAM SILEN, M.D., DIRECTOR, DIGESTIVE DISEASE RESEARCH CENTER, HARVARD MEDICAL SCHOOL

Mr. Chairman and members of the subcommittee, I am pleased to appear before you today to speak in support of the Digestive Disease Research Centers program at NIDDK. I am William Silen, Director of the Digestive Disease Research Center that is a shared effort of the facilities at Harvard University, Beth Israel Hospital, and Brigham and Women's Hospital in Boston, Massachusetts.

The National Institute of Diabetes, Digestive and Kidney Disease (NIDDK) has recently established ten digestive disease research centers to enhance the effectiveness of groups of research scientists who study digestive diseases and disorders. There are now thirteen federally supported centers across the United States devoted to the study of diseases of the digestive system and nutrition. Each of these centers brings together both basic scientists, such as immunologist and biochemists, and clinicians, such as surgeons, endoscopists, and radiologists. The centers make possible cooperative research among these investigators by making centralized resources available for research projects and by encouraging scientists to develop new investigations and collaborations in the area of digestive diseases.

This is an exceptional opportunity for me to advise you, because I can not only boast of the exciting research advances that are being made at the DD Center at Harvard, but as well, the outstanding accomplishments in gastrointestinal investigation that are being conducted throughtout the nation at the other centers of excellence in digestive research.

Using the shared facilities of Harvard University, Beth Israel Hospital and Brigham and Women's Hospital in Boston, I lead a group of investigators studying the structure and function of the smooth muscle and the epithelium throughout the digestive tract. This research may lead to a better understanding of various digestive tract processes, such as the defense mechanisms that protect the stomach and duodenum against injury from gastric acid secretions.

The center at the New England Medical Center in Boston is under the direction of Dr. Mark Donowitz, and is involved in studying 1) the processes by which materials are absorbed into and secreted out of the body through the gastrointestinal tract, and 2) the diseases that can arise from abnormalities in these processes, especially diarrhea, malabsorption syndromes, and jaundice.

Dr. Don Powell is the director of the center located at the University of North Carolina at Chapel Hill. Scientists at this center are focusing their research on diarrhea, irritable bowel syndrome, and inflammatory bowel disease. A unique aspect of this center is its collaboration with North Carolina State University's School of Veterinary Medicine, where animal models for the study of these diseases may be developed.

Dr. William Snape directs the new digestive disease research center at the Harbor-UCLA Medical Center in Torrance, California, which is devoted to the study of inflammatory bowel disease. Two areas of research emphasis are examining immunologic responses of IBD patients and mapping genetic abnormalities that may determine a person's predisposition for IBD.

Research at the center located at the Mayo Clinic and Foundation in Rochester, Minnesota is under the direction of Dr. Sidney Phillips and is focused on the control of several functions of the digestive tract, including digestion, absorption and motility. In addition, investigators at this center are studying common diseases that result when these functions are disturbed. These diseases include non-ulcer dyspepsia, functional diarrhea, irritable bowel syndrome, and constipation.

Dr. Tadataka Yamada directs the research at the University of Michigan at Ann Arbor, where scientists are studying gastrointestinal peptide hormones, which are involved in appetite regulation, digestion, motility, secretion, and nutrient absorption. Research advances from this work may help researchers better understand the role of gut hormones in the development of a wide range of illnesses, such as obesity, peptic ulcer, irritable bowel syndrome, and diarrhea.

Dr. James Christensen oversees the activities of the center located at the University of Iowa in Iowa City, where investigations are focused on the mechanisms of gastrointestinal motility, absorption and transport processes, and the neuroanatomy of the digestive tract. For example, one group of scientists is examining the effects of exercise on motility in the digestive tract. Results of this work may help to explain why long distance runners and other participants in intense exercise often experience nausea, abdominal cramps, and sometimes bloody diarrhea.

The center at Yale University in New Haven, Connecticut is under the direction of Dr. James Boyer and is devoted to the study of liver structure, function, and disease. This center studies 1) liver transport function and bile formation; 2) bilirubin metabolism and the effects of alcohol; 3) mechanisms of liver fibrogenesis; 4) blood flow to the liver and other digestive organs; and 5) the evolution of chronic liver disease treatments, including liver transplantation.

Dr. Joseph Bloomer directs the liver center at the University of Minnesota at St. Paul. Research at this center is focused in three areas: 1) abnormal liver metabolism due to both inherited and acquired liver disorders; 2) liver damage due to viral hepatitis; and 3) liver transplantation.

Dr. Francis Simon directs the hepatobiliary research center at the University of Colorado at Denver where researchers are concentrating their studies in 1) bile secretion disorders, which may be involved in drug toxicity, cholesterol gallstone disease, and jaundice; 2) disorders of liver lipid metabolism, which may cause cholesterol gallstones and atherosclerosis; and 3) liver cell injury caused by hepatitis B, drugs, metals, and liver cancer.

Mr. Chairman, since its creation in fiscal year 1984, the Digestive Disease Research Centers program has proved a fabulous window of opportunity for our field to study digestive diseases in a more coordinated, and more sophisticated manner. To continue this progressive effort, I, on behalf of the centers directors would like to encourage your subcommittee to include an adequate amount of funding for continuation of existing centers projects, and for the addition of two more comprehensive centers that would complement current programs by studying pancreatic disorders and sorely needed pediatric gastrointestinal disease research.

Thank you for the opportunity to present testimony to your subcommittee, Mr. Chairman. I am pleased to respond to any questions you may have.

STATEMENT OF THE NORTH AMERICAN SOCIETY FOR PEDIATRICT GASTROENTEROLOGY

As past-president of the North American Society for Pediatric Gastroenterology and a member of the National Digestive Disease Advisory Board, I am pleased to present my perspective on digestive diseases in children.

The number of Pediatric Gastroenterology and Nutrition subspecialists has expanded significantly over the past 10 years. There are now approximately 70 training programs whose graduates number approximately 30 per year. Members of our subspecialty address several needs: (1) maintaining health (i.e. nutrition) during the critical period of development of the gastrointestinal tract, and (2) managing specific disease entities. Our subspecialty was founded on the premise that the digestive tract of children has a distinctive physiology and is affected by unique diseases. Our patients are not "small adults", therefore research into mechanisms and treatment of digestive diseases in adults may not be applicable to children.- These aspects must be recognized so that we can institute effective management which will allow the child to attain his/her full growth and developmental potential. Practitioners of our subspecialty treat patients with disease similar to those seen by our colleagues in internal medicine, such as inflammatory bowel disease and chronic active hepatitis; these diseases, however, have features and complications particular to the pediatric population.

Despite the recent increase in the number of trainees entering the subspecialty, the manpower and research needs are still not being met. This is reflected by the continual, energetic recruitment of graduating trainees by university departments and by independent hospitals. In most medical centers, diseases of the digestive system rank second in frequency to respiratory infections.

In parallel with the need for an increase in the number of practitioners, intensified investigations directed toward basic and clinical questions must be carried out. A central theme must be to understand alterations in development of digestive tract structure and functions which are associated with the enhanced susceptibility of the immature digestive system to exogenous insults as well as various specific disease entities. In fact, immaturity of function, in and of itself, is an important area of study. Aspects of cell biology, perinatal gastrointestinal tract physiology, and biochemistry must be interrelated so that factors crucial to the nutritonal care of premature infants can be outlined. With these concepts in mind, improved methodology suitable for a study of infants and children may be developed.

The clinical entities which are referred to a specialist in Pediatric Gastroenterology and Nutrition are broad in scope. Currently, the major, frequently encountered problems are:

(1) **Provision of nutrition** for the low-birth weight infant and maintenance of nutrition for infants who have suffered a catastrophe in early life which as led to loss of a critical length of the intestine. In both of these common situations the

infant has impaired ability to digest and to absorb **nutrients.** The latter entity, termed the "short bowel syndrome" is currently managed by provision of nutrients through parenteral (intravenous) routes. The only hope for survival in these infants depends on an increase in the absorptive capacity of the **remaining bowel**, namely overgrowth of the unaffected segments. The recent refinements in the techniques of parenteral alimentation (i.e provision of the entire caloric need by vein) has allowed for improved survival of neoates in whom adequate oral feeding is not possible. However, there is a major complication of this modality - the development of liver disease with cirrhosis. This will occur in direct relationship to the duration of the parenteral infusion and is especially frequent in premature infants. Better understanding of the needs of vulnerable infants may allow the administration of appropriate nutrients and trophic substances which may more rapidly induce adaptation of the immature gut of the premature infant as well as the damaged gut of the infant with intestinal disease.

(2) The two most common forms of **liver disease** in the infant, termed neonatal hepatitis and biliary atresia, are enigmatic. We currently have no firm data as to their cause and have no specific methods of treatment. These diseases are common, occurring in approximately 1 in 4,000 live births. Their impact on the child and family is great; the financial burden is large and the lack of information is difficult for affected families to accept. The only hope for survival for children with progressive disease is liver transplantation. Since affected infants are young and undersized, surgical techniques and recruitment of donors matched in size is difficult. Approximately 40% of these die while **awaiting** transplantation. Study of the mechanisms of pediatric liver disease may lead to recognition of specific anti-viral agents or drugs which could prevent progressive heopatobiliary dysfunction.

(3) **Gastroesophageal reflux**, a very common disorder in the

newborn period, can have serious consequences. There is significant morbidity, with complications such as pnuemonia, failure to thrive, anemia, cessation of breathing, and damage to the esophagus. The cause of this disorder is unknown, however, alterations in development may be responsible. Better understanding of gastrointestinal function may allow rational use of drugs to decrease the incidence and impact of gastresophageal reflux.

(4) **Cystic Fibrosis**, which occurs in an alarming frequency (1 in every 2,000 live births) is also not specifically treatable. Affected children die of lung, heart, liver or intestinal complications. We, as pediatric gastroenterologists are frustrated by our inability to provide consistent, effective nutrition to manage the liver manifestations (gallstones, cirrhosis, bleeding) attendant to this disease.

(5) **Congenital enzyme deficiencies**, which lead to impaired absorption from the gut or improper utilization of nutrients by the liver, are managed at present by feeding specifically designed formulas. This is only partially effective.

(6) **Infectious Diarrhea**, the major cause of infant mortality in underdeveloped countries, must be more precisely investigated. A clear understanding of the intestinal response to injury as well as the intrinsic defense mechanisms is crucial to management and prevention.

Mr. Chairman, the day-to-day management of each of these diseases is a challenge for pediatric gastroenterologists. Practitioners of our subspecialty have voiced their commitment to address these issues on several fronts. Precise definition of the scope of these problems, achieved through careful epidemiologic studies is a first step. Education and training of young subspecialists in our field will create a "critical mass" effect which will provide time and environment for meaningful research. There is, at present, little outside financial support for training programs in Pediatric Digestive Disease. Consistent attention to research issues must be fostered so that new information regarding prevention and treatment will emerge. We need your support. I thank you for the opportunity to provide this testimony.

STATEMENT OF THE SOCIETY OF GASTROINTESTINAL ASSISTANTS, INC.

Mr. Chairman and members of the Subcommittee, I am pleased to appear before you today on behalf of the Digestive Disease National Coalition. I am a registered nurse clinician, assigned to a surgical endoscopic unit at the University of Maryland Hospital in Baltimore. I am also a member of the Society of Gastrointestinal Assistants and their government liaison to those organizations concerned with the prevention, treatment and control of digestive diseases through improvement and expansion of research, training and education programs.

I wish to focus my testimony today on how I see this all relating to the patients that I care for.

It is a fact. . .

One of ten Americans suffer digestive problems, twenty million have a chronic digestive disease. Digestive disorders are the Number One cause of hospitalization and surgery. This trend is partially due to the fact that many persons are reluctant to talk openly about digestive problems due to embarrassment and fear of rejection from peers, thus evading medical intervention. Our patients need help in coping with a diagnosis that they cannot understand or which is difficult for them to accept. The impact of digestive disorders on the lives of patients and their families is often accelerated due to our inability to pinpoint causes and provide hope for the future. Their one hope on the horizon is research. As it carries out its research mission, the National Institutes of Health's development of effective therapies for preventive diagnosis, and treatment of diseases within the digestive tract will touch a great segment of my patients of various ages.

Kathy, a young female patient with Crohns Disease (an inflammatory bowel disease) returns periodically for follow-up care. She wants to have a baby, but her physician has advised against pregnancy at this time. The drugs that she must take to control the disease with its embarrassing and stressful symptoms are known to be harmful to the fetus. She wants to know what is being done to find the cause for this disease, and will less toxic medicines be developed? Her only hope is a strong commitment to a fundamental research program which might answer her promise for the future or a clinical research program that might help her now. This can only be possible by the government making every effort to support research training and research career awards.

Bill is a young father of two small children who was suddenly beset with rectal bleeding and diagnosed with cancer. Advances in the field of gastrointestinal endoscopy made his evaluation less stressful due to the new flexible fiberoptic instrumentation. The ability to make the diagnosis by direct tissue biopsies at the time of colonoscopy brought prompt surgical intervention. Post-operative maintenance dosages of chemotherapeutic drugs were given. Now two years later he is cancer free and leading a normal life with his family. Periodic evaluations will guard against reoccurence. All this was made possible through the sharing of fundamental research knowledge among the Institute's investigators, and strong commitments to a comprehensive research effort.

In the geriatric population patients with diverticulosis (pockets which form on the wall of the large bowel, collect food particles and sometimes become infected), suffer recurrent abdominal pain which can interrupt their daily activities. The cause is not known, they express feelings of dispair, hopelessness and anxiety for their future. Will I be a burden? Will this get worse? Their hope is again support of research programs, and preventive educational programs.

The affects of emotions and stress known as functional gastrointestinal disease presents a diversity of symptoms in all age groups. Providing my patients with a scientific explanation of this phenomenon is difficult. It has presented in patients as a result of child abuse, drug abuse, in fellow workers as a result of stress in the work place, divorce, graduate schooling. Being a part of the MIEMS Shock Trauma Center, I see these patients presenting further life threatening complications of gastrointestinal bleeding. Endoscopy shows this to be caused by stress ulcers. The physiological explanation of all this is still not clear, the one hope on the horizon is a comprehensive research effort.

These are but a few examples of how intramural and extramural research programs throughout the Institutes and NIH filter down to the patient, the family and the nurse. The nurse is the direct care giver and the person most involved in patient assessment, planning, implementation of care and evaluation of the patients progress toward a mutually agreed goal. She makes a commitment to become a patient advocate within the health care delivery system. Patients have the right to know not only what is being done to them, but also what is being planned, prescribed and researched for them. Development of new methods of prevention diagnosis and treatment of disease can result in enormous cost savings and increased safety, especially in patients at high risk, and a more rapid return to normal activities.

There is a staggering need to identify, develop and promote digestive disease education/information programs focusing on prevention, to develop new modalities of treatment, to identify etiologies that are unknown and to continue the training of health care professionals in the field of research to accomplish these goals.

Mr. Chairman, I appreciate the opportunity to present testimony to your subcommittee on behalf of the Digestive Disease National Coalition and Society of Gastrointestinal Assistants. I am pleased to respond to any questions you may have.

STATEMENT OF SHEILA BRASS CHADWICK, HUMAN GROWTH FOUNDATION

My child has a rare growth disorder that causes dwarfism. He is one of 10,000 children who have been treated since the 1960's with Human Growth Hormone (HGH), an extracted product of donated human pituitary glands processed into injectable doses by the National Hormone and Pituitary Program (NHPP) (formerly the National Pituitary Agency) an agency of the National Institutes of Health/National Institute of Diabetes, Digestive and Kidney Diseases (NIH/NIDDK). The opportunity to achieve "normal" growth enhanced their lives and also saved our society the social welfare burden of caring for a large group of individuals destined to never reach their full potential of productivity because of the very real handicaps dwarfism imposes. Parents entered the NHPP research program confident of its value, and SAFETY.

On April of 1985, HGH supplied by the NHPP was suddenly removed from distribution by the FDA; shortly after, commercially produced HGH was also removed. Families of children who received HGH treatment learned from their newspapers that three young men had died from Creutzfeldt-Jakob disease (CJd) - a devastating, rare degenerative neurological disease - a decade after taking apparently contaminated HGH supplied by the NHPP.[1,2,3,4]

Three years earlier, nobel-laureate Dr. D. Carleton Gajdusek of the NIH had warned his colleagues that CJd transmission through HGH could occur, but no one listened or believed him. No hormone analyses were undertaken then to test the safety of HGH as currently or previously prepared. Now three deaths have taken place and the link to HGH seems irrefutable or the FDA would not have hastened to remove the drug. It is possible and likely that many more deaths will occur, and that others have occurred which were misdiagnosed because CJd is unthinkable in so young a population. Virologists have told us that any or all of the children may have been accidentally dosed with CJd causative agent, a very slow growing viral particle identified only in the past decade.[2,3] The ten thousand families whose children were treated with NHPP HGH and the three to five thousand treated with commercially processed HGH must now face the possible delayed death sentence of their children due to a drug they were told was safe. It can take decades for the symptoms of CJd to appear. There is no diagnostic technique, no treatment. Disintegration of the central nervous system usually occurs within one year following onset of symptoms.[1] Death is inevitable. Each parent of an HGH treated child asks "At how much risk is each child - my child"? What can be done to identify the children at greatest risk? Who is responsible for the massive number of potential deaths?

NIH and an interagency task force,[4] including FDA and CDC, proposed an epidemiological study to identify and locate individuals given HGH by the NHPP and to find out how many more may have already died or developed early degenerative neurological symptoms; this proposal did not include the commercial hormone recipients. Animal studies were initiated with stored batches of HGH and physician questionnaires were distributed. The first year of this study was projected to cost one and a half million dollars ($1.5). about $100 per child. However, only $500,000 has actually been appropriated from agency funds because of their shrinking research budgets. It is now a FULL YEAR since the HGH was removed by the FDA, yet no contract for the study has yet been awarded.

We believe the full funding of the epidemiological study is absolutely essential to identify those at risk, and should include recipients of commercial hormone to produce valid statistical inferences. This study will not save our children, but it will provide us with the preliminary data for further research about CJd. Additionally, because slow-growing viruses may be related to many other nerve cell degenerative disorders, current medical knowledge can be greatly enhanced by this study of a known test group with years of medical documentation through their participation in growth research administered by the NHPP since 1965.

We believe that without fully funding the NIDDK budget request of $504 million dollars our program needs as well as others will suffer. Failure to fund this study is an abrogation of responsibility to the children who received HGH from the NHPP/NIDDK.

Moreover, we support the NIH $6.1 billion dollar budget request. NIDDK has attempted to obtain funding from other involved agencies, but has had no success. Our study depends upon interdisciplinary cooperation among the scientific specialties at NIH and the Public Health Service. Although NIDDK administers NHPP programs, the NICHD and NINCDS (Child Development and Neurological Institutes) are closely involved with research on HGH recipients. Surely biomedical research should be a national priority in a nation so richly endowed with resources as ours (if, for no other reason, the benefits to our citizens and our economy are so great). Pioneering NIH studies have generated international research, which led to the creation of a genetic engineering industry producing millions of dollars of wealth through innovative biosynthetic drugs whose application would be unknown but for NIH seminal research. We need more, not less, biomedical research. Discouraging research in any of its disciplines by shrinking budgets when knowledge is expanding means for all of us, putting far into the future the quality of life that could be available tomorrow or next year. It means a generation of children suffering or dying needlessly. The current decreased funding has already produced fewer research fellows and difficulty in generating new research teams when necessary funds are lacking to complete previously undertaken studies. We stand at risk of losing a talented generation of medical scientists if we permit the decline in quality the proposed FY 1987 budget cuts and the Gramm-Rudman-Hollins Act will cause. Growth Hormone recipient families have particularly felt the brunt of retrenchment in the way the epidemiological study has been shunted around and delayed. The anxiety it has created in our parents is incalculable.

We hope Congress will use strong support language for our program needs for the epidemiology study to follow HGH recipients, although we recognize that NIH appropriations are not line-item reviewed.

Finally, what of the future of those with growth disorders? The NIDDK report to Congress endorsed formation of an Endocrine Advisory Council. Our parents believe that a Growth Disorders Advisory Board is essential to direct the future research necessary to safeguard the children who will receive treatment and participate in research. Biosynthetic growth hormone is currently being used to treat many children with growth disorders. Although current studies suggest it is safe and efficacious, what side effects may crop up ten years from now to plague these children? Ten years ago, no one would have dreamed that CJd contamination was possible from HGH. Who is overseeing the new treatments? Who is coordinating the future research for the large population of growth-disordered children? Even if it requires a separate Congressional Act comparable to the one which created the Digestive Diseases Advisory Board, we pray your Committee will consider this greatly felt need of the thousands of families with growth disorders.

Our children were pioneers in scientific exploration. They accepted the pain and the risks of research. Now, we parents of children who have taken and will take human growth hormone feel an axe hanging over our heads like the sword of Damocles. The thought is now always there, as we look at our beautiful children, that we may lose them because we tried so hard to help them. Tens of thousands of us will live with this fear for decades to come.

We are grateful for the NIH research in orphan diseases without which our children would inescapably be consigned to their dwarfism and its related disorders. We are grateful to Congress for your past support. Now, more than ever, we need your continued support.

REFERENCES

1. Testimony of Janet and Lloyd Tatlock about the death of their son Wayne from Creutzfeldt-Jakob disease, submitted to the subcommittee, April, 1986.
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3. Dr. Stanley B. Prusiner, "Prions," Scientific American, Vol. 251: No. 4, Oct. 1984.
4. Public Health Service Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease, first quarterly Report, Dec., 1985 (available from NIH Office of Health Research Reports. As of this writing award of "best and final" contract has been postponed three times.

STATEMENT OF JANICE AND LLOYD TATLOCK

Our son, Wayne, died, a helpless invalid of an undiagnosed disease on February 26, 1985. He was the oldest of four sons. When he was only a baby, the doctors told us he wasn't growing as he should. They tried vitamin B 12 shots and thyroid treatment, but that didn't help.

When he was eight or nine, our pediatrician in Jacksonville, Florida, told us he had a form of dwarfism and suggested the best center for growth abnormalities in the country was at Johns Hopkins Hospital in Baltimore. He made arrangements for us to take Wayne there and after thorough tests he was accepted as a case study by the head of this program, Dr. Lawson Wilkins. He was one of the first group of children treated with the human growth hormone extracted from the pituitary glands of cadavers.

We agreed that Wayne could be a case study. He would have an opportunity to grow that financially we could not provide as missionaries for our church. And he would be helping the doctors to provide growth through treatment for countless other children with similar growth deficiencies.

Wayne remained on this program through puberty. He reached a height of four foot eleven inches. Unfortunately his system built up antibodies to the HgH. We never felt his treatment was a failure because we knew others were helped by what the researchers learned. Wayne also received psychological counselling to help him deal with his short stature. He was a warm and loving person with an outgoing personality, and led an active life.

In March of 1984, he began to have a problem with his balance. It finally became so acute, he was given medical leave from his place of employment, and consulted, first our general practicioner and then on his advice, a neurologist. Repeated tests and consultations revealed no abnormalities but his sense of balance became so poor that he progressed from a walker to a wheelchair. He came to live with us so that we could care for him. Finally he could no longer feed himself or sit erect. His speech at first became slurred, and then almost unintelligible. The doctors told us that they knew it was a degenerative neurological disease, but were unable to pinpoint a diagnosis or a treatment.

I repeatedly asked if it could be related to his growth problem, but they found no connection. I contacted Dr. Robert Blizzard, who had succeeded Dr. Wilkins on Wayne's case at Johns Hopkins to see if any of his other case studies had similar symptoms. He had recently completed a follow-up study of some of his former patients, and he said he had not heard of any one like Wayne at the time.

On the morning of Wayne's death, his jaws locked and we could not force the liquids that nourished him into his mouth. The nurse inserted a feeding tube through his nose so he would not dehydrate. He simply stopped breathing that night. We were glad he could die so peacefully.

Dr. Blizzard contacted us shortly after Wayne's death; two other young men had died of similar symptoms and had been diagnosed as having Creutzfeld-Jakob disease, a degenerative disease of the central nervous system that usually attacks only older adults. What did these young men have in common? They had all been recipients of injections of the pitiutary extract and had died of a virus carried by a diseased gland that produced a disease called "Creutzfeld-Jakob", a virus that laid dormant in the gland for twenty or more years. HgH treatments were suspended until further studies could be made.

We do not want to see other young men and women die as Wayne did. Neither do we want to see them denied their potential growth because they cannot receive the treatment they need.

Our plea is that you grant the funds necessary so that research may continue so that our wish may become a reality.

STATEMENT OF LEE DUCAT, PRESIDENT AND EXECUTIVE DIRECTOR, NATIONAL DISEASE RESEARCH INTERCHANGE

I am Lee Ducat, founder of the Juvenile Diabetes Foundation and Founder of the National Diabetes Research Interchange, which recently became the National Disease Research Interchange. I presently am President and Executive Director of NDRI.

I have served on the Diabetes Commission and two National Diabetes Advisory Boards. I am now serving on the Task Force on Organ Transplant.

On behalf of NDRI, let me state our appreciation of this opportunity to present our views to this Committee on fiscal year 1987 appropriations for the National Institutes of Health and particularly the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK).

Since 1975, the federal government has played an active role in improving care for people with diabetes and in determining the causes of this disease. In fiscal year 1985, the NIH funded approximately $210 million for research on the cause of diabetes and its treatment. We at NDRI applaud this commitment.

Diabetes affects some 11 million people and each year about 500,000 new cases will be diagnosed. Diabetes with its complications is the third leading cause of death by disease. Its complications include many major disabling conditions such as blindness, heart disease, kidney disease, stroke and amputation.

Clearly, the role of the federal government is critical in determining the cause of diabetes and improving the treatment of those with the disease. About one-half of NIH research support is in the NIDDK, but other sources of major research funding are the National Heart, Lung and Blood Institute (NHLBI), National Eye Institute (NEI), Division of Research Resources (DRR), National Institute of Child Health and Human Development (NICHHD), and the National Institute of Neurological, Communicative Disorders and Strokes (NINCDS).

Since its creation in 1950, the NIDDK has made great strides through basic research. These laboratory successes are meaningfully applied to improving the nation's health through clinical studies and trials and programs of technology transfer, information dissemination, and coordination with professional and voluntary groups. 1986 is the first year of operation for NIDDK which had been part of the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases. We at NDRI share in the excitement of the separation of NIDDK from NIADDK.

We recognize the strains that have been placed on the federal budget in recent years, but the fact that diabetes continues to pose a serious threat to our nation's health must not escape us. The desirability of exercising fiscal austerity should not be lost to this fact.

Therefore, NDRI recommends a NIDDK budget of $504 million for FY 1987. This budget would enable the Institute to support approximately 637 new grants, the same number as in the current year at their full direct and indirect cost.

Without this budget, many major initiatives will have to be deferred. Those initiatives include career development awards, initiatives in instrumentation and initiatives dealing with minority health. Other important initiatives which can be funded with our recommended budget include work on transplantation of endocrine tissue, initiatives to obtain transplant tissue, expansion of diabetes and endocrinology centers, a trial to prevent kidney disease complications of diabetes through intensive therapy and a trial related to kidney transplantation for children.

NDRI is very familiar with these new initiatives. Our program is the only one in the world that coordinates the procurement of human tissues and organs, and preserves and delivers these tissues and organs to researchers throughout the country. NDRI has made it possible for investigators who never had access to human tissues to now obtain a regular supply.

Since 1980, we have provided a highly individualized, reliable and easily accessible service to the medical investigator at the national level.

To date, NDRI has delivered over 20,000 tissue samples. We currently serve 208 researchers supplying human tissue samples to meet the requirements of 475 scientific protocols.

On April 30, 1986, NDRI coordinated a conference to "Assess the Use of Human Tissues and Organs in Research in Other Disease Categories."

I believe the conference underscored the fact human tissue is critical and vital to corroborate the results of the use of animal models. Moreover, we found that human tissue is vital in its use as an alternative resource to animal tissue. Indeed, for most of the major disease categories very few, if any, animal models exist. I submit that the human model is needed to explore diseases like lupus, cystic fibrosis, AIDS, and diabetes.

We therefore again respectfully request that our recommended level for NIDDK funding be given every possible consideration. Furthermore, NDRI wishes to express its support for an appropriation level of $6.079 billion for fiscal year 1987 for NIH. This recommended level of funding would be consistent with our national commitment to biomedical research and would translate into an appropriate, sound, and progressive level of NIH research activity which accurately reflects its vital mandate.

On behalf of NDRI, I would like to thank you for this opportunity to present our views.

Statement of Elizabeth E. Goffredi, R.N., A.A.S., L.P.N., Member, American Diabetes Association

I represent 13 million diabetics across the nation as a medical professional, representative of the Diabetes Associations, and as an insulin-dependent diabetic myself for 34 of my 38 years. I am in the unique position of seeing the ravages of this disease personally as a patient myself, as Director of Nursing, and as a world-famous research patient, and it is a grueling experience. It is documented that diabetes was present in ancient Rome. Today, hospitals are filled with diabetic patients. Health costs are astronomical and it devastates the family physically, emotionally, socially, and financially. It is a heartbreaking and agonizing disease that affects the spouse, friends, and co-workers as well.

It has no mercy on its victims and is now thought to be caused by a virus or defect in the individual's immune system, so anyone can be stricken with it. It is increasing at an alarming rate of 6% a year. It has been found to follow measles or mumps or traumatic injuries in football or auto accidents. 20% are dramatically afflicted in childhood or as young adults and 80% become diabetic in the prime of life or in later years. It is a great personal burden and costs the Federal Government over $10 billion annually in disability costs as stated by a Presidential Document published in the Federal Register on November 8, 1983.

Let's work together to put an end to this disease now and please be generous because some day all of our lives may depend on your decision. We must push ahead, for research will brighten our future and unlock the door to a cure. Only research can bring about a cure, prevention, and better treatments for the complications of this horrible disease. If I have the courage to be a human "guinea pig" for the prevention of diabetic blindness, I am sure you, as strong, healthy government leaders have the courage to support diabetes with the appropriation of funds.

This disease is the 3rd leading cause of premature death and it is a silent tragedy because it does not get the needed attention that an earthquake, volcano, or tornado gets, and yet it is equally destructive and deadly. It destroys the body from the inside, piece by piece and affects every system of the body. It is cruel and ruthless, and attacks the rich as well as the poor. It stops at nothing and robs the body and brain of its usefulness.

In 1973, at the age of 27 years, I was diagnosed as having proliferative diabetic retinopathy, in spite of a strict diet, multiple insulin injections, and prescribed exercise. This eye disease is characterized by eye hemorrhages and abnormal growth of new and fragile blood vessels on the retina which often leads to retinal detachment and ultimately blindness. The eye disease was incurable then and it progressed to the point where I could not read or drive a car.

I was asked to volunteer in a Diabetic Retinopathy Study at Wills Eye Hospital in Philadelphia in hopes of finding a cure to prevent blindness. Officials of the experiment would pick one eye and treat it with either an argon or xenon laser beam, known as photocoagulation, and the untreated eye would serve as a control. I considered their offer very carefully knowing the risks, unwanted side effects, and that I would eventually go blind if nothing was attempted.

I decided to take the chance and when I arrived for the treatment, I was told that the better eye would be treated with the argon laser. They sat me on a stool and strapped in my head. I could feel each time the laser struck the retina. However, it was tolerable and no anesthetic was given. I had over 1,100 photocoagulation shots to the retina. The eye watered profusely during the treatment because the eyepiece kept becoming dislodged and they had to frequently replace it. After a time, the blood vessels had been successfully sealed off and the bleeding had stopped. For about 6 weeks my vision in that eye appeared clouded and then I had a clear view. Years later, when the study was completed, the argon laser, which they used as an experiment on me proved to be the treatment of choice.

Later, my worst eye, the untreated one, began to hemorrhage frequently and I experienced a large blowout. I had been told previously that nothing could be done for that eye. I also experienced double vision because diabetes had affected a nerve which controls one eye muscle. Laser treatment for this eye was an impossibility since the disease had progressed too far. "I was desperate and willing to try anything" when my doctor told me of an experimental surgical procedure called a vitrectomy. However, he warned me that it was a highly risky procedure. Following the surgery, the bandage was briefly removed, I was able to see some light and as time went on, I started to see the outline of objects. I am very fortunate because both experiments restored my vision to 98%. I believe in research and in miracles, but others, in more recent times, are not as fortunate, and some I have spoken with are completely blind in their early 20's even after undergoing the same procedures. Much still remains to be done.

Following my bout with possible blindness, the diabetes attacked my kidneys. I became tired, then exhausted, and nearly collapsed. I lost weight and became very frail and thin. At times I could hardly feed myself and had to be assisted. I then became bedridden and helpless. The color on my face turned gray and my hair became brittle. When in the final stage of kidney failure, you also experience nausea and vomiting after every meal. I was prone to fractures because the calcium level dropped due to further deterioration and my specialist placed me on AlternaGel, an over-the-counter medication to counteract and prevent fractures. The AlternaGel costed us $60. per month and it was not covered by insurance because a prescription was not needed. Electrolytes which include sodium, potassium, chloride, and carbon dioxide became unbalanced and at this point, the disease becomes life-threatening and life hangs in the balance.

I was admitted to Thomas Jefferson University Hospital in Philadelphia and I chose CAPD (continous ambulatory peritoneal dialysis) because the use of hemodialysis by machine requires the use of an anticoagulant called Heparin, and anticoagulants can not be used on me because these drugs would cause hemorrhages again and result in permanent blindness. A dialysis catheter was surgically implanted into my abdomen and I was required to perform sterile dialysis exchanges 4 times a day. The greatest danger with this is peritonitis which is an infection of the lower body cavity. It is extremely dangerous, difficult to treat even with antibiotics, and life-threatening especially in diabetics and all kidney failure patients because they have a lowered resistance to fight infections. Bacteria thrive and multiply rapidly in a sugar medium and all diabetics, no matter how controlled, have some sugar in their urine, blood, or tissues and also have delayed and difficult healing.

I know what it is to wait with anticipation on a kidney transplant list. I know what it is to feel frustrated and disappointed when the phone rings and it is not the hospital calling with a kidney match. Some patients wait as long as 6 to 8 years for a donor organ. At present, there are over 7,000 Americans hoping and waitfor a transplant - a second chance at life.

On March 7, 1985, my prayers were answered, but others are not so fortunate. The chief transplant surgeon phoned me and I was elated to get the chance at a transplant even though diabetics are always greater surgical risks. I also knew that I may face possible rejection of the organ at anytime in the future.

Several weeks after my transplant, my Mother almost suffered a heart attack because of the added stress and strain she went through seeing me in intensive care and hooked up to numerous tubes and machines. My illness still affects my wonderful husband with migraine headaches, an ulcer, insomnia and a rapid heart rate of over 100 beats per minute. These are all caused by emotions due to worrying about a diabetic wife. He has also seen me unconscious with my eyes wide open and unresponsive on the bathroom floor. The rescue squad was unable to revive me and he feared I would die. Prolonged unconsciousness can result in permanent brain damage, but again, I was fortunate. Please do not allow this to happen to anyone else or this country may lose some of the most dynamic and intelligent assets that this nation has.

As you know, impaired circulation in the feet and legs caused by diabetes results in tissue death known as gangrene and amputation of the extremity is the final treatment to save a life. Recently, Kate Smith who sang "God Bless America" had her leg amputated due to diabetes. I understand that Jackie Robinson, a great professional baseball player died prematurely following a stroke caused by diabetic vascular disease. If diabetes can kill a great athlete, what can it do to a person with a sedentary lifestyle such as executives or those who sit for long periods daily? Jimmy Cagney, a well-known actor, suffered and died from complications of diabetes. Is equality in the pursuit of life for all?

Being world-famous and winner of a college scholarship for straight A's will not save my life nor my body from further deterioration, but money placed into the hands of earnest medical/surgical researchers will. I have already outlived my predicted lifespan by 14 years and I am now age 38, but I am determined to beat the odds.

I have endured a great deal myself and risked my own life. I am referred to as "the walking miracle" or "the bionic woman". I have dedicated my life to advancing diabetic research and seeking a cure. Therefore, bio-medical research should continue agressively through the National Institutes of Health. I am certainly doing my part, but I can not do it alone. As tax-payers, voters, American citizens, and human beings, we need help which only you can provide. I am desperately asking for your support before this disease tolls on all of us one by one. It is far better to appropriate funds for finding a cure now than spending U.S. dollars for disability payments to those who are unable to work. A cure and improved treatments for the complications are the miracles that we yearn for. Please join us and help us wipeout diabetes altogether. Please be noble and take a stand in our behalf. This great nation has the power and ability to make things happen, and together we can achieve this goal. I have great faith that each and every one of you who are understanding, fair, and just officials will speak positively for us and be our voice in the government. You have a great opportunity to stop this dreaded disease. I am sure that God and your own heart will guide your decision, and I pray that you and your loved ones will never be stricken with diabetes. This is your chance to support humanity and all Americans who trust and respect you as representatives of all the people.

STATEMENT OF STEPHEN G. PAUKER, M.D., SOCIETY FOR MEDICAL DECISION MAKING

Senator WEICKER. I would like the two witnesses for the Library of Medicine to come up at the same time, Dr. Stephen Pauker, and Dr. Edward Shortliffe.

Dr. PAUKER. Mr. Chairman, it is a great honor and opportunity to appear before you today. I am professor of medicine at the Tufts University School of Medicine. I am chief of the Division of Clinical Decision Making in the Department of Medicine of the New England Medical Center. I am a founding member of the Society for Medical Decision Making.

I wish to express my strong support for the good work of the National Library of Medicine in the field of Medical Informatics and to endorse the budget proposed by the ad hoc group for health research funding and by the Director of the National Library of Medicine [NLM].

Informatics is the science of collecting and organizing and utilizing medical knowledge. At the present time, virtually all training in medical informatics is funded by the NLM. The requested budget of $2.4 million would provide funding to an additional 30 trainees.

It is important to maintain medical research and training, and I strongly recommend the establishment of centers of excellence in medical informatics. Informatics offers the promise not only of future benefits, but some of the work for decisionmaking consultation services.

As you know, the practice of medicine is fraught with uncertainty. Much of the physician's skill and judgment centers on the application of retrospective data and literature to the individual patients. Our consultation service offers advice to physicians dealing with unusual and complex individual decisions.

For example, we saw a 95-year-old lawyer, who had a new spot on his lung detected after examination at one medical center, and he was told that he was too old to be treated. At another center, he was told to have immediate surgery. Our group developed a decision with our informatics model suggesting that the use of therapy was an option not even considered. In fact, he received that therapy, and he did very well.

Over the past decade, we have performed some 400 such analyses of problems that cover the full range of medicine, from pediatrics to geriatrics, some psychiatry to surgery. We have considered the optimal workup for patients suspected of having AIDS, the necessity for renal biopsy, and the necessity for routine cerebral angiography in polycystic kidney disease.

We have allowed patients to participate in decisions involving their care in domains ranging from prenatal diagnosis to coronary bypass surgery. Thus, the fledgling signs of medical informatics can even now improve patient care.

The medical profession has recognized the necessity of making basic changes in the educational process, but one critically constrained resource is the number of health professionals trained in medical informatics and the amount of research that can be mounted.

Given the substantial present and even greater future investment our Nation will be making in research in health care delivery, it would seem wise to invest adequate funds to improve the decisionmaking process that would provide the physician with the scientific basis to deal with the inevitable uncertainties in medicine.

PREPARED STATEMENT

I hope thatthis testimony will be useful to you as you consider the budget of the NLM and its request for moneys for extramural research, for training, and for the establishment of centers of excellence in medical informatics.

Thank you.

Senator WEICKER. Thank you very much, Dr. Pauker.

[The statement follows:]

Statement of Stephen G. Pauker

Mr. Chairman and distinguished members. It is a great honor for me to appear before you today. I am chief of the unique Division of Clinical Decision Making in the Department of Medicine of the New England Medical Center and am Professor of Medicine at the Tufts University School of Medicine. I am a founding member of the Society for Medical Decision Making, a multi-disciplinary organization of over 600 professionals engaged in practice, teaching and research in medical decision sciences.

I wish to express my strong support for the good work of the National Library of Medicine in the field of Medical Informatics and to endorse the budget proposed by the ad hoc group for health research funding and by the director of the National Library of Medicine. Within that proposed budget, I shall address my remarks toward the program in medical informatics and toward training programs in medical informatics research.

It has been gratifying to see the strong leadership your committee as provided for research and training in this arena in past budget cycles. As we all know too well, medicine is facing new and more difficult challenges at an ever increasing pace. One of the greatest challenges has been the explosive increase in technology and information. Certainly, the expansion of medical knowledge offers the promise of improving patient care and increasing the quantity and quality of life. However, before that promise can become a reality, medicine must develop the scientific basis for controlling that information and transforming it into useful medical knowledge. The science of collecting, organizing and utilizing such knowledge has recently been called Medical Informatics.

Within the past several years, the American Association of Medical Colleges has issued two reports emphasizing the central role that medical information science will hold in the next century. In 1984, the GPEP report recommended that medical schools designate an academic unit for institutional leadership in the application of information sciences and computer technology to the general professional education of physicians. A recently released follow-up report recommended that medical informatics should be integrated into the medical curriculum, that an identifiable locus of activity be established in each academic medical center and that the National Library of Medicine should continue to be the federal standard-bearer with respect to funding training, career development and research in medical informatics. That report suggested that the establishment of centers for excellence in medical informatics would be the most effective means of approaching the country's manpower needs in this arena.

As the need to train physicians to use and control medical information has become more pressing, it is paradoxical that the number of programs training physicians in these skills has decreased over the past several years. As academic medical centers are asked to realize that medical informatics must be a central feature of any educational program responsive to today's technologies, no less to even conservative estimates of the size of the medical knowledge base in the professional lifetimes of today's physicians, the requirement for trained faculty will surely increase. The need in 1986 is to train future medical faculties and to retrain today's faculties in the management of medical information. Sadly, our medical colleagues in Western Europe have devoted significantly more resources to medical informatics than has the medical establishment in the United States. Departments of Medical Informatics are not uncommon in European academic medical centers but have yet to appear in force here, in part, because of the lack of individuals trained to teach and perform creditable research in this domain.

At the present time, virtually all training in medical informatics is funded by the National Library of Medicine. For the past six years I have been privileged to be the director of one of the five current programs. Our fellowship program is directed at young physicians planning careers in academic medicine. On average, our program graduates two such physicians each year. A recent meeting of NLM sponsored trainees in medical informatics allowed an exciting exchange of ideas and the opportunity to reinforce this career path. Unfortunately, the total number of NLM trainees is under thirty. On average, most training programs require over three years of didactic work and supervised research. Thus, the total national output of the programs is quite small with respect to even short-term needs. If each academic medical center tries to establish a separate unit and if each unit requires from three to five trained faculty members to be effective, then it will be a very long time before these five programs can produce sufficient faculty. The requested budget of $2.4 million (a doubling of current levels) would provide funding for an additional 30 trainees. I believe that level to be optimal given the current faculty level available for staffing those programs.

If we are to be effective in recruiting bright young physicians into this career path, we must provide an intellectually stimulating community and a stable environment for research. Once again, the lion's share of funding for research in medical informatics is provided by the NLM. Unfortunately, many excellent projects go unfunded and talented young investigators are lured to other domains that provide a higher likelihood of stable funding. Sadly, the lack of a large vigorous scientific community within either academic medical centers or NIH itself makes it more difficult for young investigators in medical informatics to establish themselves professionally. Because medical faculties have few medical informaticians, criteria for academic advancement rarely include an appreciation of the special problems of basic research in this field, where the time frame for individual projects can be very long and where there is often little opportunity to publish in the standard prestigious journals. Thus, there is a need to foster the establishment of a sense of community and a set of role models for potential faculty members to emulate.

Unfortunately, the immediate need for faculty in most academic medical centers will dilute the size of the community in even current foci of research below a critical mass; the isolated physician will be most unlikely to compete successfully for research grants. Thus, in the short run, despite the pressures to disseminate medical informatics into each academic medical center, it will be important to maintain critically niduses for research and training. It is for this reason that I strongly support the establishment of centers of excellence in medical informatics. The $3.2 million in the proposed budget would provide core funding for perhaps four centers. Along with the proposed increase of $1.5 million (to a total of $5.6 million) for extramural research grants in medical informatics, these funds should go a long way toward establishing medical informatics as a viable academic career choice.

Lest the committee assume that medical informatics offers promise only for the future of medicine and little applicable to the practice of medicine in 1986, allow me to summarize some of the clinical work performed by our Decision Making Consultation Service. Our current research activities are funded largely by the extramural program of the NLM.

The practice of medicine is fraught with uncertainty--uncertainty about diagnosis, about prognosis, and about the implications of various therapeutic alternatives. Although the literature of medicine is organized by the responses of groups of patients and often describes the prognosis of the average patient in a given clinical setting, as physicians we almost never treat the mythical average patient. The clinician deals with individuals and much of the physician's clinical skill and judgment centers on the proper adaptation of the past experience with well controlled groups of patients to the uncontrolled prospective experience of the individual. Our consultation service offers advice to physicians dealing with unusual and complex choices in individual patients. The techniques of clinical decision analysis provide the physician with a deeper understanding of the clinical problem and the impact of the inevitable uncertainties of practice.

For example, we were asked to consider the optimal treatment for a 95 year old lawyer who had a new spot on his lung detected at an annual examination. One medical center advised him that he was too old to be treated; a second center, one specializing in cancer treatment, advised him to have immediate surgery. He was finally seen in our hospital and our group was asked to render an opinion. Unfortunately there are few data about the treatment of lung cancer in the very elderly. Thus, we developed an decision analytic model to explore this question. Our analysis suggested that optimal therapy would be empiric radiotherapy -- an option not even considered before we analyzed the case. In fact, he received that innovative therapy and did well. Over the past decade we have performed some 400 such analyses on problems that cover the full spectrum of clinical medicine -- from pediatrics to geriatrics, from psychiatry to surgery. Our analyses usually provide both the referring physician and the patient with a deeper understanding of the clinical problem and sometimes with an unexpected therapeutic plan. We have considered the optimal diagnostic workup of patients suspected of having AIDS, have written about the lack of necessity for routine renal biopsy in patients with nephrotic syndrome and the lack of necessity of routine cerebral angiography in patients with polycystic kidney disease, and have allowed patients to increase their participation in decision involving their medical care -- in domains ranging from prenatal diagnosis to coronary bypass surgery. The central point about these examples is not the specific recommendations but that the fledgling science of medical informatics can even now improve patient care.

In summary, medical practice is just beginning to face what will perhaps be its greatest challenge -- an explosion of knowledge and information which is proceeding at a pace which even now outstrips the cognitive styles taught in our medical schools. The medical profession has recognized the necessity for making basic changes in the educational process but one critically constrained resource is the number of health professionals trained in medical informatics and the amount of research that can be mounted in that domain. The National Library of Medicine is recognized as the world leader in the domain and should be given sufficient resources to allow the field to grow in an orderly fashion. The current pace would seem too slow, but unbridled enthusiasm would also be inappropriate. In 1986, there are so few competent medical informaticians that excessively high funding levels will not provide appropriate marginal gains. On the other hand, I believe that the budget proposed by the Director of NLM and endorsed by the ad hoc committee has been well designed and will increase the pace of professional development while still maintaining order and efficiency. I endorse that proposal enthusiastically and solicit your continued support for these important goals.

Thank you again for the privilege of providing you with additional information about the present and future importance of medical information science in improving medical care and providing an environment in which clinicians can make better decisions about the use of medical resources and the design of therapeutic plans.

Given the substantial present and even greater future investments our nation will be making in medical research and health care delivery, it would seem wise to invest adequate funds to improve the decision making process and to provide our physicians with a scientific basis for dealing with the inevitable uncertainties in medicine and for optimizing the use of medical knowledge. I hope this testimony will be useful to you as you consider the budget of the National Library of Medicine and its request for monies for extramural research, for training, and for the establishment of centers for excellence in medical informatics.

STATEMENT OF EDWARD H. SHORTLIFFE, M.D., PH.D., AMERICAN COLLEGE OF MEDICAL INFORMATICS

Senator WEICKER. Dr. Shortliffe.

Dr. SHORTLIFFE. I am Dr. Edward Shortliffe, associate professor of medicine at Stanford Medical School, and also a Ph.D. computer scientist. I direct a program rather like Steve's on the west coast, where we are focused on training young people to become workers at the interface between medicine and computing.

Although I represent today the American College of Medical Informatics, a young organization of people in this field who are elected to fellowship, it seems that since you have my written testimony that I will take the little time I have today to give sort of a personal statement. I changed it a bit just by being here today and listening to the comments that have been made by others who have testified before you because I recognize that in a way our plea will seem somewhat different from any others that come to you on behalf of the NIH and medically related research funding in that we don't identify with a specific disease, or even a specific organ system.

On the other hand, I was quite aware, as I listened to the remarks from others, of the general relevance of the kind of work in the National Library of Medicine and other computer related work in NIH for all of the areas of health and health care delivery in all the instances.

Just one example that occurred to me was the young lady who testified on behalf of interstitial cystitus, who pointed out that it is a poorly understood and poorly known disease. Many patients see 8, 9, or even 10 physicians before they find one who is familiar with it.

It seems to me that it is important to emphasize that in medicine today it is not just a matter of finding new knowledge and creating new information, but getting it to the people at times and in places where they can actually make use of the significant amount of new knowledge that NIH and the research community has available.

Even if one looks at the President's budget this year of $4.9 billion for NIH, one might ask, what is a reasonable percentage of that kind of an investment to expend on disseminating knowledge and information out to the practitioner and trying to make sure that people have the tools and the information in their hands when they make the decisions about patient care.

If one said, 1 percent, even that would be some $50 million, and yet the total investment right now in research in medical informatics at the NIH, divided between the National Library of Medicine and the Biomedical Research Technology Program, the division of research resources is well under $25 million.

So I am here to make a plea for increased research and funding for that research at the National Library of Medicine, with a request of $72.9 million budget. This would be an increase of $16.5 million over the President's budget for fiscal year 1987. The reasons for that request are outlined in our written testimony.

The Biomedical Research Technology Program, one branch of the Division of Research Resources, which has funded the computing resources necessary to the biomedical computing research community, be increased to $51.8 million, which is an increase of about $7.3 million over the 1986 appropriation.

These are relatively small amounts of money when one looks at the investment in computing at the NSF, or in the Department of Defense where some $200 million per year are being invested in computer science research, none of which is available to biomedical researchers, who are immediately told that if they have good ideas for new knowledge and new kinds of computing activities that are relevant to biomedicine, then you should go to the NIH where there are much more limited resources available.

An ironic side effect of that reality is that we are finding many bright young medical computing specialists who would like to pursue careers at the interface of medicine and computing, as is true in many of the other fields you have heard about today, are being drawn into defense related, or nonmedical computing research activities because that is where they can get the kind of funding that they need for their research activities.

We argued the medical relevance in our written testimony, but I think that it is important to stress that getting information and the best kind of decisions to support physicians and health care planners, and other health providers, is as important to their care as finding out the answers to some of the unanswered questions.

PREPARED STATEMENTS

It doesn't do any good to develop new knowledge if the people who need it can't get a hold of it, and this is what this field is directed at.

Thank you.

Your prepared statement will be included in the record at this point along with other statements submitted in the record on appropriations for the National Library of Medicine.

[The statements follow:]

STATEMENT OF EDWARD H. SHORTLIFFE

Mr. Chairman, I come before you today on behalf of the American College of Medical Informatics, a body of elected fellows who represent specialized expertise in the area of medical computing and its role in promoting the health of the nation. I am a member of the Executive Committee of that organization and have been professionally active in the field of medical informatics since the late 1960's. I am currently an Associate Professor at Stanford Medical School, where I combine the clinical practice of internal medicine with training and investigation in medical informatics.

Thank you for this opportunity to speak on behalf of the field and to comment on the crucial role that federal research support, particularly from the National Library of Medicine (NLM) and from the Biomedical Research Technology Program of the Division of Research Resources, has played in nurturing this young but promising discipline. It seems clear that our nation must recognize that important medical research involves many activities in addition to the traditional wet bench laboratory or the clinical trial. Just as banks cannot practice modern banking without financial software and airlines cannot manage modern travel planning without shared databanks, it is increasingly difficult to practice modern medicine without the use of information technologies. Health professionals recognize that a large percentage of their activities relate to information management -- for example, obtaining and recording information about patients, consulting with colleagues, reading the scientific literature, planning diagnostic procedures, devising strategies for patient care, interpreting results of laboratory and radiologic studies, or conducting case-based and population-based research. It is, however, society's overriding concern for patient well-being and the resulting need for optimal decision making that tends to set medicine apart from many other information-intensive fields. That concern gives a special significance to the effective organization and management of the huge bodies of data with which health professionals must deal.

Medical informatics is the rapidly developing scientific field that deals with biomedical information, data, and knowledge -- their storage, retrieval, and optimal use for problem solving and decision making. It accordingly touches on all basic and applied fields in biomedical science and is closely tied to modern information technologies, notably in the areas of computing and communication. The emergence of medical informatics as a new discipline is due in large part to advances in computing and communications technology, to an increasing awareness that the knowledge base of medicine is essentially unmanageable by traditional paper-based methods, and to a growing conviction that the process of expert decision making is as important to modern biomedicine as is the fact base on which clinical decisions or research plans are made.

Although the medical informatics field is young, its clinical and research impact is already being felt. Hospital information systems, which provide communication and information management functions in medical institutions, are increasingly being installed. Physicians can search the entire pharmacopoeia in a few seconds, using the information provided by a computer program to anticipate harmful side effects or drug interactions.

Electrocardiograms generally receive their initial analysis by computer programs, and similar techniques are being introduced for interpretation of pulmonary function tests and a variety of laboratory and radiologic abnormalities. Microprocessor systems routinely monitor patients and provide warnings in critical care settings such as the intensive care unit or the operating room. Both medical researchers and clinicians regularly use computer programs to search the medical literature, and clinical research would be severely hampered without computer-based data storage techniques and statistical analysis systems. Advanced decision support tools are also beginning to emerge from research laboratories and are likely to have a profound impact on the way medicine is practiced in the future.

Despite the early impact of medical informatics, substantial fundamental obstacles remain. Necessary progress is inevitably dependent on the quality of basic research in acquiring, representing, and flexibly reasoning about the diverse information relevant to biomedicine (e.g., instrument data, images, and direct human observations of patients). Such progress is further dependent both on the orientation and training of scientists who choose to pursue careers in medical informatics and on assuring their access to advanced computing and communications resources.

The National Library of Medicine has a special obligation to help insure that informatics principles are effectively developed, disseminated, and applied -- both for the well-being of patients and to help biomedical professionals in their clinical and research activities. NLM has recognized these responsibilities in medical informatics, and its programs have ranged from training new investigators to implementing state-of-the-art technologies and supporting research into improved methods for bringing current knowledge and information to health professionals and to their patients. In light of these broad responsibilities in promoting the effective use of information technologies in medicine, the NLM is increasingly viewed as the national center for education, service, and research in the medical informatics field.

The programs of the NLM have been complemented by computer technology support from the Biomedical Research Technology Program (BRTP) in the Division of Research Resources at NIH. Together these two agencies are largely responsible for support of all basic and applied research in medical informatics. Their impact has been important, but limited, because of a history of severely constrained funding for extramural research in this area. Both agencies merit increased funding so that needed expansion of research in all aspects of the field can be achieved. My goal today is to comment on why I believe medical informatics is important to health and medicine and why it is only beginning to be understood as a discipline by the medical community and the public. I will also mention a few barriers to achieving the field's potential and suggest ways in which enhanced federal funding can help overcome them. My specific requests will be for an NLM appropriation of $72.9M, an increase of $16.5M over the proposed FY 87 President's budget of $56.4M, and for a BRTP FY 87 budget of $51.8M, an increase of $7.3M over the amount previously appropriated for FY 86.

It was over 20 years ago that the National Library of Medicine recognized that the traditional view of libraries as repositories for printed materials failed to recognize the power of new information management technologies and the potential for computers to play a more active role in accessing information and, eventually, in helping us decide how to apply it to specific patient problems. If libraries are to be viewed more broadly as knowledge sources, then the library of the future will increasingly depend on technologies that make vast amounts of information both accessible and useful. The success of the MEDLARS and MEDLINE systems for accessing the medical literature, plus the other online databases at the NLM, are testimony to the foresight and capabilities of those who years ago realized the potential of the technology and the changing needs of the medical community. The capabilities of modern technology continue to enable powerful distribution methods that can overcome the bottlenecks of paper- and publication-based approaches to information dissemination.

In recent years the NLM has continued its encouragement of innovation in the area of medical information management, despite an extramural budget which has been remarkably low when one considers the importance to medicine of the research issues being addressed. The Library has recently introduced new programs in Medical Informatics Research and in Integrated Academic Information Management Systems (research towards distributed computer-based information systems to serve health professionals in large academic health centers). Research in medical informatics has largely centered on how to best represent biomedical knowledge in computer systems, how to best access that knowledge, and how to develop computing systems that can actually use knowledge to reason about clinical problems so as to help with diagnosis or to give advice about specific complex patient management problems. You may ask when and if such advice systems will be practical, useful, and cost-effective. Although a few limited decision support systems of this type are already in use, a realistic answer, quite simply, is that no one is quite sure when truly general and powerful systems will appear. Such is the nature of research activities. Yet small research expenditures in this area, when they lead to results, have the potential for high leverage due to the high costs of health care.

It is too easy to forget that computer science research activities often address fundamental problems, problems not dissimilar to those faced in a traditional medical research lab. New knowledge in medical computing, as in other disciplines, often develops slowly and incrementally. Only occasionally are the issues reducible to engineering tasks -- problems of simply applying well-understood techniques to a new medical problem area. More frequently we are guided by an idea, or a recent research result, which itself holds promise for providing another piece of the puzzle. The NLM has recognized the complexity of the tasks being proposed, and has developed the principal federal research program that directly addresses fundamental issues in medical informatics. Its recent identification of the need for research to create a unified medical language system shows a keen understanding of the kinds of problems that limit the capabilities of current online systems. The National Library of Medicine proposes to develop the unified language system in collaboration with medical specialty groups, university research centers, and other relevant industrial and governmental scientists. Even though such a development is a large one, just as was the original MEDLARS project, it offers the chance to forge direct connections between the language of patient care and that of the scientific literature, thus reducing the gap between what is known and what is practiced. I heartily endorse their new emphasis on work in this area.

Research efforts such as those supported by the NLM, however, cannot be effectively undertaken without additional funds. Computing research is expensive, both because of the advanced technology which should be used, and because of the high labor costs. The American College of Medical Informatics accordingly recommends a total NLM appropriation of $72.9M in FY 87, an increase of $16.5M over the FY 87 President's budget of $56.4M. This incremental investment will restore funds for basic medical library services (some $3M) and provide resources for advanced research on information dissemination and distribution technology. The latter efforts are necessary so that the results of research, obtained so effectively by NIH at great expense, can be made available to the people who will benefit from what is being learned.

Before I leave the subject of the NLM, I would like to say a few words about another major factor limiting the growth and effectiveness of Medical Informatics research activities -- the lack of well-trained scientists to undertake the work. I suggested earlier that it is a mistake to think of medical informatics as the simple application of known computing techniques in clinical settings. Although computer science skills form one key element of this interdisciplinary field, effective research also requires, for example, practical knowledge of medicine, biostatistics, epidemiology, decision sciences, health economics, and medical ethics. The need for specialized training in medical informatics, with novel curricula encompassing the fields mentioned, has recently become recognized by increasing numbers of organizations, spearheaded through a joint effort by the National Library of Medicine and the Association of American Medical Colleges (AAMC).

Recognizing the need for trained academicians and researchers in the field, the National Library of Medicine began to support medical informatics graduate training programs in 1972 and funded 10 such centers through the beginning of this decade. Due to funding restrictions, however, support is now limited to post-doctoral trainees and the number of funded programs was reduced in the last three years to only five -- a step in precisely the wrong direction! With medical schools looking for increasing numbers of trained specialists in medical informatics who can begin academic and research programs at their institutions, they are discovering that researchers with formal training in the area are a rare breed. There is a severe need for talented people trained at the interface between medicine and computer science. The National Library of Medicine is well poised to increase its role in this area if funding permits enhanced training programs and the establishment of Centers of Excellence.

There is another interesting and frustrating reason why individuals with computer science expertise often turn away from the medical arenas in which their talents are particularly needed. It is, quite simply, easier to get research funding, and access to advanced computing equipment, if one works in nonmedical research areas of interest to the National Science Foundation and the Department of Defense. Federal policy, through these agencies, has fully acknowledged the importance of "high tech" in guiding the country's economic future. NSF and the DOD have had major infusions of funds to support innovative research and to improve computing facilities at the nation's universities and research labs. Major supercomputing facilities funded by the NSF have been developed at several sites. In the absence of recognition that there is promising "high tech" research activity in the medical arena as well, NIH funding for computer research has been limited and there has been an effective drain of talented people away from medical computing research. This failure to appreciate the importance of advanced biomedical computing research facilities is evident in the cuts proposed in the FY 87 budget of the Biomedical Research Technology Program (BRTP) of the Division of Research Resources (from $44.5M appropriation in FY 86 to $42.4M requested for FY 87). Approximately half of the BRTP budget supports advanced centers in the area of biomedical computing. The agency funds large facilities that could not be supported by single research grants or by NLM and are, instead, shared among groups of investigators who are undertaking similar sponsored research. Examples of such resources include the PROPHET system which provides computer-based drug modeling services for a national community of pharmaceutical chemists, the BIONET computing resource which assists molecular biologists with DNA sequence analyses, and the SUMEX-AIM computing resource which serves a community of medical informatics researchers who are applying artificial intelligence techniques to medical problems. These are only a few examples of the kinds of biomedical computing activities made possible by the Biomedical Research Technology Program; many of the projects sponsored by the National Library of Medicine, for example, use equipment that is provided through a BRTP resource.

It seems to me that this symbiosis between BRTP and NLM is sensible in its effective use of limited computing research dollars. Yet each agency depends on the other to a large extent. A reduction in support for a BRTP resource would shift costs to the individual users' sponsored projects budgets at best, but might even make the required research computing environment unavailable. It is shortsighted to reduce or limit the opportunities for the Biomedical Research Technology Program to efficiently introduce shared state-of-the-art computing facilities into the medical research community. The American College of Medical Informatics accordingly recommends a $51.8M FY 87 appropriation for BRTP, a $7.3M increase over the FY 86 appropriation of $44.5M. The $7.3M will restore the 10% downward negotation of grants that is reflected in the President's FY 87 budget, enable the program to fund the same number of centers in FY 87 as it did in FY 86 (otherwise slated to be reduced by one), and allow a modest $3M expansion for new resources in biomedical computing.

Thank you again for the invitation to raise these important issues with you today. In light of the nation's substantial annual investment in medical research and health care delivery, it would appear only prudent to invest a significant proportion in programs related to techniques for managing and distributing medical knowledge and data. I hope I have provided information that you will find useful in considering our request for increased support of Medical Informatics through the extramural funding activities of the National Library of Medicine and the Biomedical Research Technology Program.

STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION

The Medical Library Association (MLA), founded in 1898, has a membership of approximately 5,000 individuals and institutions including libraries of academic health centers, hospitals, and industrial firms. The purpose of this professional organization is the promotion of excellence in health through access to information for those in patient service, education, and research. The Association of Academic Health Sciences Library Directors (AAHSLD) represents those libraries whose parent institutions are the medical schools accredited by the Association of American Medical Colleges. Its purpose, as well, is to seek the widest and most efficient dissemination of health-related information. The position statement in behalf of the FY 1987 budget for the National Library of Medicine (NLM) represents the opinions of MLA and AAHSLD.

We are most appreciative of past efforts by the Senate Appropriations Subcommittee on Labor, Health and Human Services in preserving a program at the National Library of Medicine that can adequately support the health professions in maintaining and improving our nation's health.

Though recognizing the national imperative reflected by the Deficit Reduction Act of 1986, the Medical Library Association is convinced that the President's proposed FY 1987 Budget for the National Library of Medicine is not acceptable relative to the role it has in safeguarding access to information by practitioners, researchers and educators. When such access is impaired, the nation is not well served.

Our recommendation, therefore, is for an appropriations level of $73,000,000. That is an increase of $16,500,000 over the President's proposal, or $13,500,000 over the current service level. Our primary concern is with the maintenance of the Library's basic operation, since the consequences of inadequate support would be felt in every part of the country. We would like to urge an increase of $3,000,000 for these basic services, i.e., an appropriation of $59,500,000.

Absent such support, the ensuing consequences are bound to be detrimental to the entire health community. The National Library of Medicine's role as the court of last resort for the availability of pertinent literature and as active disseminator of information would be severely compromised. While there will be no let-up in the phenomenal increase in the biomedical literature, a growing percentage of this information would become inaccessible, either because the NLM could no longer acquire it, or because the processing, cataloging and indexing functions would be altered or delayed, and because the related MEDLARS system improvements could not be made.

A very recent letter received by a colleague of a prominent MLA member from a consulting physician at St. Luke's Regional Medical Center in Boise, Idaho, describes a life-threatening situation with a 2 1/2-year old boy, and how his life was saved when the hospital librarian conducted an immediate MEDLINE search of titles relating to therapy to be applied in this particular circumstance. Abstracts were printed for several of the more promising titles, and although many of the journals were not available in the St. Luke's Regional Medical Center Library, the abstracts contained much of the life-saving information. The letter, cosigned by the child's mother, concludes:

> Allen is now on the road to full recovery. Without the aid of the computer-based search I would not have known how to proceed in the short time available for me to find an answer. We are indebted to the Pacific Northwest Regional Health Sciences Library Service and the National Library of Medicine for making available a data base that can help answer the tough questions. (Letter appended).

Closely related to the basic function of making health information easily accessible, is the obligation to preserve the literature now held by the National Library of Medicine. This obligation was recognized by the Congress in the FY 1986 appropriations, but, in order to combat the rapid deterioration of valuable material, it is our recommendation to increase funds for this task by $600,000 for FY 1987.

The last component of NLM's intramural program we wish to call to your attention is that most important task of creating a Unified Medical Language system. This initiative deserves a high priority since the lack of a common vocabulary is a major impediment in constructing and implementing a system that will allow for easy communication, without hazardous translation, between and among researchers, practitioners, members of specialty societies, federal agencies, insurance companies, and academic staff. We believe that an appropriations level of $3,000,000 for FY 1987 is required to begin work on this project in any meaningful way.

We emphasize the success of the National Library of Medicine's Extramural Program, particularly advancements made possible by the Medical Library Assistance Act. Among the most visible is the Regional Medical Library Program, whose biomedical communications network has created cost-efficient ways of disseminating information, training librarians, and encouraging the establishment of health related libraries. We recommend an increase for the Regional Medical Library Program of $500,000.

Another important area of the Medical Library Assistance Act is the grants program. Resource Improvement grants and Resource Project grants are frequently the sole means for advancing the application of information technology to services provided for health professionals. Our recommendation is for an increase of $900,000 for this grants program, including additional funding for publication projects.

The Integrated Academic Information Management Systems program is another NLM high priority initiative that is now ready for Phase III development. The purpose of IAIMS is to link the many related but unconnected files, records and databases of academic medical centers (including hospitals) into one unified configuration. The resulting sophisticated electronic communications system will allow clinicians, researchers, educators, students and administrators rapid access to all information in a medical center. Phase I and II provided for planning and testing. For Phase III, the implementation phase, we recommend an increase of $3,000,000.

Thanks to NLM's vision and Congressional support, the Medical Informatics program has been nurtured for ten years. Drawing on expertise from a variety of fields, it is designed to develop computerized systems that allow interactive modes of communication between the computer and the clinician or scientist. We recommend that additional funding of $4,500,000 be provided, allowing NLM to give stable research support to investigators in the amount of $1,500,000, and with the remaining $3,000,000 to begin the establishment of Centers of Excellence in Medical Informatics at selected university campuses.

In order for the future of medical informatics investigation to be placed on a firmer foundation, training programs in informatics research must also be funded. Therefore, we recommend an increase of $1,000,000 for Research Training in the Medical Informatics program.

Letter From Dr. Mark Ellis and Sandy Denowh (Allen's Mother)

March 14, 1986

Ms. Connie Schardt
Idaho State Coordinator
Idaho State Library
325 W. State Street
Boise, Idaho 83702

Dear Connie:

As a professional faced with many difficult decisions, I would like to relate a recent experience. This case illustrates how immediate access to current information through MEDLINE can impact patient care.

The case involves a 2½ year-old boy, named Allen Denowh, who suffered a hemorrhage into the brain's inner cavity, the ventricles, at birth. As a result he developed a blockage to the flow of spinal fluid necessitating placement of a shunt to drain the spinal fluid from the inner cavity into the abdomen (a ventriculoperitoneal shunt). With this shunt Allen has grown and developed normally.

About six months ago, I consulted on Allen's case because the end of the shunt in the abdomen had become infected. His infection responded well to antibiotics and removal of the old shunt. Prior to placing a new shunt, Allen received a very important antibiotic to prevent the new shunt from becoming infected. This antibiotic is called Vancomycin and has unique properties for preventing these infections. In particular, it extends the coverage to include all the penicillin resistant Staphylococci.

Problems began close to the end of a twenty minute infusion of Vancomycin. To my knowledge Allen had never received the drug before. In front of his very distraught mother, Allen developed a very intense erythemetous (red) rash and lapsed into unconsciousness. An episode of profound hypotension (low blood pressure) was the cause. Fortunately Allen spontaneously recovered, was shunted, and returned home to a normal life.

I was called one afternoon recently by Allen's pediatrician to consult on his case again. Allen had been admitted to St. Luke's Regional Medical Center in Boise, Idaho in a near comatose state and body posturing strongly suspicious of a new shunt infection and meningitis. An aspiration of spinal fluid from the shunt revealed "gram positive cocci" on gram staining. This staining procedure allows an initial evaluation of the probable bacterium causing the infection. In this instance the stain was strongly suggestive of Staphylococcus, a bacterium that frequently infects these shunts. Also, many of these Staphylococcal bacteria in this setting are resistant to penicillin and penicillin-like drugs. In fact, the only drug I knew to be effective, without question, was the Vancomycin to which Allen had reacted so violently.

You can imagine the dilemma the Denowh's and I faced. Their 2½ year-old son would die in a matter of hours without treatment and the only drug I knew to use was one that nearly caused a fatal reaction six months previously.

Before proceeding I contacted our hospital librarian, Pam Spickelmier, who ran an immediate MEDLINE search of titles over the past several years relating to therapy in this circumstance. A number of promising titles were then selected and abstracts printed for review. Many were in journals we do not have available in our library. From the abstracts I was able to learn that no alternative therapies were available. I also learned that the drug reaction previously experienced might be avoided with an alteration in the infusion rate of the drug. After full discussion with the parents, we decided to proceed and slowly administered the drug. To our delight Allen did not have a recurrence of his reaction and tolerated the full dose.

Allen is now on the road to full recovery. Without the aid of the computer based search I would not have known how to proceed in the short time available for me to find an answer. We are indebted to the Pacific Northwest Regional Health Sciences Library Service and the National Library of Medicine for making available a data base that can help answer the tough questions.

Sincerely,

Mark Ellis, M.D., F.A.C.P.

Sandy Denowh
(Allen's Mother)

ME/ghb

SUBCOMMITTEE RECESS

Senator **Weicker**. Thank you very much. I thank you both very much for your testimony.

The subcommittee will stand in recess.

[Whereupon, at 1:40 p.m., Tuesday, April 29, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, May 1.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

THURSDAY, MAY 1, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Specter, Proxmire, and Burdick.

NONDEPARTMENTAL WITNESSES

STATEMENT OF MARILYN PRICE SPIVACK, EXECUTIVE DIRECTOR, NATIONAL HEAD INJURY FOUNDATION (MASSACHUSETTS)

Senator WEICKER. This morning, we will continue our public witness hearings on the National Institutes of Health [NIH], and to include the National Institute of Neurological and Communicative Disorders and Stroke [NINCDS]; the National Institutes of Immunology and Infectious Diseases; the National Institute of Child Health and Human Development [NICHD]; the National Eye Institute; the National Institute of Dental Research; and the National Institute on Aging.

I would request again that all witnesses adhere strictly to the 5 minutes as indicated by the clock as a courtesy not to the Chair, but to their fellow witnesses.

Why don't we get going on matters ahead of us by having Marilyn Spivack, the executive director of the National Head Injury Foundation [NHIF].

Ms. SPIVACK. Senator Weicker, I would like to bring up Rob DeMickless, who suffered a head injury in 1980 and his mother, Mrs. DeMickless, who works with the foundation. I want to thank you for the opportunity to be here again this year. I want to request your help again to raise some questions regarding what we are going to do and spend in the future for all those disabled by head trauma and who are still not recognized or served by health care rehabilitation services and systems.

You know me first as a mother. My daughter was head injured in 1975, and she was the reason for the NHIF. As cofounder and director, I represent 14,000 members in 30 States with over 350 chapters.

We really need this committee to bring attention to the plague of head injury. It is as serious, catastrophic, and costly as any well-known disease. The time has come, because each year, we add 50,000 severely injured young people to this population. Hospitalizations range from 500,000 to 700,000 each year. One hundred and twelve thousand children are victims of head injury each year.

Trauma, indeed, is the last major plague of our young. It kills more Americans under age 34 than all other diseases combined and has taken more lives than all our wars. We lose 4.1 million years of productivity annually, and yet we give so little attention, funding, to this catastrophe.

It causes physical, intellectual, psychologic, and cognitive definites. Two weeks ago, we were very happy to have our first convention here in Washington. Our members made 116 congressional calls, and we told our Senators and our Representatives of the needs of each one of their States.

We were received with enthusiasm and interest. Senators Danforth and Kennedy were our luncheon speakers, and both have family members with head injuries. Senator Kennedy's son had a minor problem this summer, but Senator Danforth's niece had a severe head injury, causing major disabilities.

She requires extended rehabilitation services thousands of miles from her home so that she may regain some independence. I would say most of the members on this committee would have to send their loved ones far from their homes if they had enough insurance coverage or they were extremely wealthy. In most States, we are still without systems of care and services.

Jim and Sarah Brady have come on board as our spokespersons. Mrs. Brady spoke of their tragedy with eloquence and sadness. She described their own struggle with rehabilitation, their life changes, and their loneliness. She recognizes and appreciates all the care and concern and rehabilitation that Jim has had. They both recognize that because of their unique position, he has had benefits that very few people have.

We are here today to urge this committee to fully support the recommended budgets for all the programs that were established to meet the needs of all disabled people. We hope these programs can meet our needs, also. We spend billions of dollars each year saving the lives of head trauma victims in acute care, and then we dump them.

As a parent, I am terribly frustrated at an administration that generates all the statements to the private sector that people with disabilities deserve the right to opportunity, to independence and equality of life, and then work so hard to strip those budgets, those programs.

Then they offer very few incentives to train the exhausted families, which adds to their own trauma. We need you to know that our loved ones are discharged from hospitals far too soon while needing extended rehabilitation on home management services.

Families must spend years acting as if they were trained therapists in all disciplines without rest or relief until either the head injured person dies or the caretaker succumbs to severe illness caused by severe problems, anxiety, and stress. Often, families try to maintain heavy responsibilities along with maintaining usual jobs and homes and caring for other children.

Often times, they must help their head-injured loved one re-enter a community totally ignorant of the problems. Re-entering a community that does not know how to accept or serve the consequences of head trauma causes further heartache and failure. Our family units are also at tremendous risk. So many end up also financially devastated.

You listened and opened agency doors for us through language. The OSERS was worked up 1 year ago and is now a working tool. We are effecting change at the State and local level, but only in a few areas. We need full funding of $1,379.4 million for section 110 of the basic State rehabilitation services, or we will have a useless agreement. We are very heavy on the language. We are weak on implementation. We hope you would fund NIH for its full $49 million and fund the Centers for Disease Control as recommended by the National Rehabilitation Research Committee.

We are also working with other agencies under Health and Human Services. Without adequate funding for programs recommended by CCDD, we can stay home and watch our loved ones continue to regress in inappropriate placements. We don't think that is a cost-effective approach, and we know you certainly don't think so.

We are going to ask you for a certain amount of requests to support research and training of head injury rehabilitation by allocating funds to develop areas of cognitive therapies, behavior modification, psychosocial skills, and vocational training. We urge the category of the disability for traumatic head injury and all relevant agencies in order to establish eligibility and funding reimbursements. We need to track patients and clients for assessments of needs so that services and programs may be developed.

We request of you that you ask an interagency working committee of all agencies under Health and Human Services in the Department of Education to gather available information so that we may link existing resources and help develop a national system capable of delivering care and rehabilitation services for head-injured people.

Finally, we would ask you to direct health care planners to study and create a funding strategy to make such a system work. Our burgeoning Federal deficit threatens to destabilize our entire economy. Knowing that you agree that correction of that problem cannot and must not be borne so heavily by the disabled, the ill and the elderly, you and your committee gives us all hope for the next few years.

Thank you, Senator Weicker.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. We will insert your statement in its entirety in the record.

[The statement follows:]

STATEMENT OF MARILYN PRICE SPIVACK

The National Head Injury Foundation, Inc. (NHIF) is a growing organization of 30 State Associations, 315 chapters and 14,000 members providing support, information, education and advocacy for individuals suffering brain damage after head injuries. Once again, we want to emphasize that head injuries account for 500,000 hospital admissions each year and of these, 50,000 - 70,000 people are left with moderate to severe disability. Thousands more experience "minor" disabilities. The tragedy of traumatic brain injuries is multiplied by the fact that two-thirds occur to people under age 35. In fact, head injury is the most common cause of death and neurologic disability in the young. The report published by the Committee on Trauma Research, "Injury in America", refers to injuries as the "last major plague of our young".

This committee has been of enormous help to us, survivors, families and concerned professions. Your legislative report language of 1984 led to the significant report of agencies under Health and Human Services (HHS) and the Department of Education of their activities relating to research training and service delivery surrounding the issues of Traumatic Brain Injury (TBI). The report was submitted and the NHIF added its' comments to that report. The result of that report was positive as it immediately led to an increasing interest and response to the NHIF communications with agencies under the Office of Special Education and Rehabilitative Services (OSERS), Interagency Committee on Handicapped Research, Social Security Disabilities Administration (SSDA), National Institute of Communicative Disorders and Stroke, National Institute of Mental Health, and Developmental Disabilities.

On May 14, 1985 NHIF entered into a cooperative agreement with OSERS. That Agreement has become a valuable working document that is already producing an increased awareness and interest in research, training and dissemination of information at the Federal and State levels. At this time, five NHIF State Associations have signed similar agreements and 23 states are working closely with their Department of Rehabilitation to implement head injury registries, needs assessments, training of counselors and special educators, and to study and plan for appropriate implementing and funding of a coordinated system of service delivery and case management. These same states are also working with members of the state legislatures for necessary authorizations and appropriations.

SPECIAL CATEGORIES. In 1984, Congress requested the report to address the need of establishing a specific category of disability for head injury and the utilization of that category by the relevant federal and state agencies. Over the past year, much discussion on this subject has taken place between the NHIF and several agencies including the Department of Education, Rehabilitation Services Administration (RSA), and the Social Security Administration. Other than RSA, to date no agency has listed TBI or Head Injury as a separate category of disability. Most importantly, the new SSDA listing of mental impairments does not single out head injury as a category. SSDA has added commentary to define appropriate methods of testing and evaluation. The NHIF is working with SSDA to disseminate education among social security evaluators, adjudicators, and physicians. NHIF will continue to urge the establishment of a specific category. We feel that a categorical listing is essential to encourage research, training and service delivery. Further, recognition by SSA and all pertinent agencies of "brain damage secondary to head injury" as a category will define the nature of the disability and track the needs of people with head injuries.

It is the purpose of the NHIF testimony this year to comment on some of the issues outlined above and to review the negative impact that the decreases in funding proposed by the Administration will have on people suffering disability from traumatic brain injury. We wish to add our voice to all those representing all disabled people asking that our country's disabled not be required to shoulder a disproportionate burden in the quest for deficit reduction.

REHABILITATION AFTER HEAD INJURY. The availability of "early" rehabilitation services after traumatic head injury has improved greatly over the past six years for a small percentage of survivors. The problem begins when the head injured person is discharged from the rehabilitation hospital to a community ill-prepared to provide the long-term services required for each individual to reach his or her full functional potential. The private sector has begun to develop such programs, but in general, they are expensive and available only to those with workman's compensation, private insurance coverages or to the beneficiaries of large insurance settlements. At the present time, there are no states with fully implemented systems of care providing appropriate programs and services leading to increased independence.

Although such a comprehensive system does not exist, there are hopeful signs that the situation is changing. Through the efforts of the NHIF and its' State Associations, and because of the expression of concern from both the House and Senate Subcommittees, there is an awareness of the problem which did not exist previously.

Some State Agencies with assistance from NHIF State Associations have taken it on themselves to seek funding at State levels, but it is abundantly clear that most states will be unable to implement new programs, and those just started will be in jeopardy if the budget for Vocational Rehabilitation State Grants is reduced to $1.1

billion for FY 87 as the Administration proposes. We join with the Consortium for Citizens with Developmental Disabilities (CCDD) and the National Rehabilitation Coalition (NRC) in requesting $1,379.2 million for this program.

SPECIAL DEMONSTRATION PROGRAMS. Since rehabilitation of head injured individuals is a relatively new field, Special Demonstration Programs under Section 311 of the Rehabilitation Act are essential to "expand and improve" rehabilitation services for this population. Under NHIF urging in 1984 and 1985, Head Injury was included as a specific priority category under this program. Five new projects may be funded at the average cost of $115,000 each. Under the President's budget request, these projects as well as others for other disabilities may not become a reality. Current projects would also be threatened. This committee is sympathetic with the critical importance of demonstrating new methodology and demonstration projects to improve vocational potential. We strongly endorse supported employment. It is the model of future hope for all severely impaired by traumatic head injuries. We strongly recommend the funding of $30.60 million for this program.

REHABILITATION TRAINING. In all rehabilitation, training of personnel is the most critical element in providing effective services to disabled people. Nowhere is this more true than in the rehabilitation of head injured people whose special programmatic needs are only beginning to be appreciated. By reducing the FY 87 congressional appropriation for rehabilitation training to $15 million, the Administration will make it impossible for RSA to institute any new initiative in this area. We urge the Committee to recommend funding of $32 million and, if achieved, request that RSA set aside specific funds for training of personnel in head injury rehabilitation.

EDUCATION OF HANDICAPPED CHILDREN. P.L. 94-142 (State and Local Grant Programs) is the backbone of special education programs for handicapped children. It is estimated that each year 110,000 children age 0-14 suffer head injuries caused by motor vehicle accidents, falls and child abuse. Clearly, most of these children will require special programs funded under P.L. 94-142. Reducing the funding level to $1,135.1 million will stop any progress in this area. We agree with CCDD that an appropriation of $1,435.6 million is necessary to allow Departments of Special Education to meet their responsibilities toward disabled children.

SPECIAL EDUCATION PERSONNEL DEVELOPMENT. As with rehabilitation programs, special education programs require trained personnel. This is particularly true when teaching a head injured child whose disabilities do not fit neatly into categories most educators are accustomed to. Because there are very few special education teachers knowledgeable about head injury, the NHIF has had a Special Education Task Force. The result of that effort has been published in a manual and a series of teaching conferences are planned. The first NHIF Special Education Conference was held in Massachusetts on December 5, 1985 for the N.E. Region Special Educators. We urge the Department of Education to set aside specific funds to train educators about head injured children. Clearly, that will not be possible if this budget is cut to $48 million as the Administration proposes. We strongly support an appropriation of $74 million.

DEVELOPMENTAL DISABILITIES. Since developmental disability includes individuals mentally handicapped prior to age 22, almost 50 percent of disabled head injured persons may fall into this category. The State developmental disability programs, if fully implemented, would provide the types of services required by head injured young people who "fall between the cracks" of other agencies. We recommend an appropriation of $56.5 million for FY 87 for the developmental disability basic state grants. Even at this level, the major burden will fall on the states for implementation.

INDEPENDENT LIVING SERVICES, Part A & Part B. Unfortunately, the programs have been specifically directed toward individuals with physical disability and thus most head injured people with cognitive and behavioral dysfunction have not been served. The NHIF urges RSA to encourage the development of I.L.C.'s for head injured people with or without physical disability as eligible for the Independent Living Services programs. To do this will require, at the very least, an appropriation of $26 million. We are also in full support of the CCDD in urging the appropriation of $30 million to continue the activation of Part A of Title VII of the Rehabilitation Act to provide for a comprehensive program of services for those individuals too severely handicapped to be eligible for current vocational rehabilitation services.

NATIONAL INSTITUTE OF HANDICAPPED RESEARCH (NIHR). If progress is to be made in rehabilitating individuals who are head injured back to productive lives, it is essential that new and innovative approaches in this area be developed. We are particularly interested in studies on cognitive retraining, use of computers, neuropsychological evaluation, psychosocial and behavioral remediation, pharmacologic therapies and innovative approaches to vocational retraining. Because of limited funding, the investigator/initiated research program was able to fund only a small percentage of applications. Funding at $39 million will seriously affect current projects when the need is to increase valuable rehabilitation research.

We recommend an appropriation level in FY 87 of $49 million. The NHIF expresses deep concern regarding the need to develop a system of coordinated care for victims of traumatic brain injury. We would ask this committee to allocate new moves to intensify research and propose the development of model systems of care.

Appropriations have not kept pace with neurological research opportunities. According to the 1985 CNS Trauma Report, the past decade has witnessed a new and improved understanding of the incidence and pathophysiology of secondary central nervous system insults for hypoxic, arterial hypertension and elevated intercranial pressure. This has allowed for altered therapeutic approaches and better outcome. We, according to Dr. Murry Goldstein, are on the threshhold of major advances in basic neuroscience. To cut back funding is to dramatically halt research that would negatively impact this important area for decades. According to the report "Injury in America", 4.1 million pre-retirement lives are lost each year to injury. 112 million Federal dollars were spent in FY 80. Head injuries are the major cause of such catastrophic disabilities. The NHIF fully supports the FY 1987 recommendation of CCDD of $505.0 million for the National Institute of Neurological and Communicative Disorders and Stroke.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH). We have talked to the NIMH director concerning the behavioral, emotional and psychosocial dysfunction suffered by many head injured individuals. The NHIF feels that research in the mechanisms causing these disabilities, as well as therapeutic techniques and pharmacologic intervention leading to remediation are within the purview of NIMH. We support the CCDD recommendation of $272.0 million for research, $27.6 million for research training, and $26 million for clinical training.

HEALTH CARE FINANCING ADMINISTRATION (HCFA). (Medicaid-Medicare.) Currently, under the DRG systems patients with TBI are often discharged from the acute-care hospital prematurely without adequate rehabilitation. The patient oftentimes is transferred to a rehabilitation hospital. Utilization Review Boards restrict treatment under rigid time frames relating to patients' physical disability - medical requirements. Therefore, it has become essential for the HCFA to not only recognize TBI as a diagnostic category but also to establish funding levels for therapeutic techniques such as cognitive remediation, behavior modification and memory retraining as well as extended physical therapy, speech therapy and occupational therapy, psychological training.

REHABILITATION ACT OF 1973, AS AMENDED
($ in millions)

Program	FY86 Appropriation	FY86 Post Sequestration	FY87 Authorization	Administration FY87 Budget	Coalition's Recommendation
Basic State Grant	$1,190.0	$1,145.0*	Pending	$1,100.0	$1,379.4
Evaluation (Sec. 14)	2.0	1.914	Pending	.6	2.0
Training	27.0	25.839	Pending	15.0	32.0
National Institute of Handicapped Research	44.0	42.108	Pending	39.0	49.0
Innovation & Expansion	9.0	8.613	Pending	9.0	9.0
Independent Living					
Comprehensive State Services, Part A	11.0	10.527	Pending	---	30.0
Centers for Indepen. Living, Part B	23.0	22.011	Pending	22.0	26.0
Services to Older Blind Individuals, Part C	5.0	4.785	Pending	---	5.5
Service Projects:					
Client Assistance	6.7	6.4119	Pending	6.3	7.5
Special Demonstration Projects	20.2	19.33	Pending	14.6	30.6
Projects with Industry	15.2	14.5464	Pending	13.0	18.0
Special Recreation Programs	2.2	2.1054	Pending	---	4.5
Helen Keller National Center	4.3	4.1151	Pending	4.2	5.5
Archit. and Trans. Barriers Compliance Board	1.97	1.89	Pending	1.97	2.5

*This represents the cost of living reduction for section 110.

Senator WEICKER. Would you like to introduce those you brought with you?

Ms. SPIVACK. Robert DeMickless. Robert had a head injury in 1980. He has been really searching and been denied all kinds of services. So here you have a young man who certainly could be helped by the supported work and method, but cannot get such help.

He has been denied over and over again Social Security benefits, and his problem is a story in itself. His mother Alice DeMickless, our legislative liaison with the CCDD makes many trips here to the Hill. I am sure they would be happy to answer any questions you would have.

Senator WEICKER. I don't have any questions for the purpose of the hearing, but I certainly would be interested to know what seems to be the problem, and why Robert cannot receive help. Is that something my staff can work on? We certainly would.

Ms. SPIVACK. Would you like me to talk to your staff about such?

Senator WEICKER. I certainly would. I would like to find out where the problem exists, both as to helping you individually, but indeed, there must be other people like yourself that have the same barrier. I would like to know what it is all about.

Mrs. DEMICKLESS. There are thousands like Robert.

Ms. SPIVACK. We have been working with Social Security disability. We have tried very hard to get a head trauma policy put into place. What we have been able to accomplish this year is commentary in the Social Security mental impairments to describe methods by which these people should have been evaluated an assisted, but we are not anywhere near home.

Senator WEICKER. I think that what you probably ought to do is to sit down with Dr. Bongard here, even as you leave. Let Steve get the facts together on this matter, all right?

Ms. SPIVACK. Thank you, Senator.

Mr. MICKLESS. Thank you very much.

Senator WEICKER. Thank you.

STATEMENT OF ARTHUR FALEK, PH.D., MEMBER OF THE EXECUTIVE COMMITTEE, HUNTINGTON'S DISEASE FOUNDATION OF AMERICA

Senator WEICKER. The next witness is Dr. Arthur Falek, member of the executive committee of the Huntington's Disease Foundation of America.

Dr. Falek?

Dr. FALEK. I am honored to have this opportunity to report to the Appropriations Committee, both as a member of the newly created combined Huntington's disease family's organization and as a psychiatric geneticist working with large populations of patients with Huntington's disease and their families.

My testimony is to emphasize the importance of maintaining current funding requests to support the research activities on Huntington's disease at the National Institutes of Health.

As a scientist involved in several areas of study in human behavior genetics, I have concern about projecting support for funds to investigate one genetic disorder over another. I do not, therefore, appear before you as a sponsor of the genetic disease of the month, but rather as a scientist who sees an important opportunity to develop a methodology developed for Huntington's disease to identify the basis for a large number of genetic disorders.

Of the more than 1,600 currently reported genetically transmitted diseases, approximately one-third have a major effect on the nervous system. This reflects a large proportion of genetic information used in the development and functioning of the brain.

Neuropathologic studies at autopsy in patients with Huntington's disease provide evidence that this disorder depletes the brain of small neurons in particular regions. The molecular genetic evidence, on the other hand, was derived from the DNA and the chromosomes of different tissues, the white cells of the blood, and the lympocytes of the skin. This information was first reported by Dr. James Gusella in 1983 at the Huntington's Disease Center Without Walls in Boston, who identified a molecular marker on a specific chromosome, chromosome 4, tightly linked to the gene for Huntington's disease.

It is now possible to use the observed molecular genetic patterns in family members to identify not only affected individuals, but, as well, presymptomatic carriers of the gene who will develop this disorder sometime later in their lifetime.

This will provide at risk family members with presymptomatic information on whether they are free of the gene for Huntington's disease, as will be their children and their children's children. Two-thirds of family members, particularly those in the childbearing years, desire such information.

This approach provides the methodology to search for the gene and the many other inherited disorders where the chromosome location is unknown and where the direct gene products are unavailable for evaluation and potential therapy.

The ethical issues encumbered in providing definitive information to at-risk individuals provided prior to any evidence of clinical illness has been an area of continuing discussions by both family members and the research community. Because of the long, ongoing relationships between members of the scientific community and members of family organizations, the ethical issues are being directly discussed.

One is whether it is appropriate to provide testing and outcome information to all individuals who request it, including those at-risk individuals who are markedly depressed with a high potential toward self-injury or suicide if the test results indicates the person is a gene carrier.

For the presymptomatic gene carrier, who will be available to help them over the longer haul? There is, at present, no treatment or cure for this devastating illness.

Molecular genetic studies with Huntington's disease as well as the procedures we employ to provide information and counseling to members of families with this disease will be the basis for the progression in our advancement with other genetically transmitted disorders where the gene locus is unknown and no treatment or cure is identified.

In particular, Huntington's disease is the prototype for other late type onset disorders with evidence of genetic transmission, including Alzheimer's disease, familiar amyotrophic lateral sclerosis, and stroke due to cardiovascular accidents. Earlier on-site psychiatric disorders include schizophrenia and manic depression.

For Huntington's disease, the identification of a molecular linkage marker to the gene not only raises the immediate potential of a presymptomatic test for at-risk family members but of eventually isolating the gene. Once the gene composition is known, it should be able to determine its pathophysiology to the disorder. Huntington's disorder provides a unique paradigm for the orientation of many disorders and potential where the mode of transmission is problematic.

Once methods become able to screen gene products, this may lead to the opportunity for gene therapy. An interesting and currently theoretical question is how to insert the normal functional gene into relevant tissue where it would act to correct the basic defect.

At present, no gene treatment for any human disease has been achieved, but this is the direction of modern medicine. Since population genetic studies have determined that all of us are carrying at least a minimum of seven genes that negatively impact on our health and survival, it is most important from both an economic and health viewpoint that the National Government support studies of methods to initially identify, and, in the long run, control or cure the most deleterious of these disorders.

The standard for positive health outcomes is available with Huntington's disease, and I urge your support through a continued level of funding for research investigations as suggested by the National Committee for Research and Neurological Communicative Disease of approximately $553 million and the Coalition for Research and Mental Health at the National Institutes of Mental Health of more than $200 million. Thank you.

PREPARED STATEMENT

Senator WEICKER. Dr. Falek, thank you very much, and I appreciate your testimony. We will insert your statement in the record at this point.

[The statement follows:]

STATEMENT OF DR. ARTHUR FALEK

Huntington's disease is both a neurological and psychiatric disorder. I am honored to have this opportunity to report to the Labor, Health and Human Services, Education and Related Agencies Appropriations Committee of the United States Senate both as a member of the Executive Committee of one of the major Huntington's disease family associations (Huntington's Disease Foundation of America) and as a psychiatric geneticist working with a large population of patients with Huntington's disease and their families. My testimony is to emphasize the importance of maintaining current funding requests to support the research activities on Huntington's disease at the National Institutes of Health in particular at the National Institute of Neurological and Communicative Disorders and Stroke and at the National Institute of Mental Health.

As a scientist involved in several areas of study in human behavior genetics, I have concern about projecting support for funds to investigate one genetic disorder over another. I do not appear before you as a sponsor of the genetic disease of the month, but rather as a scientist who sees an important opportunity to develop a conceptual framework founded on an interrelationship of new methodologies that have the potential of identifying the basis for a large number of genetic disorders. My request for your support for the maintenance of funds to study Huntington's disease is that molecular genetic research with this classical, usually late onset, autosomal dominant, neurodegenerative disorder characterized by progressive, involuntary movement and dementia has introduced new strategies that provide initial data on the molecular basis for Huntington's disease as well as new biomedical approaches to investigate the etiology of a vast variety of other genetically focused disorders.

The ages of onset for these disorders occur not only in infancy and early childhood but as well at different time points throughout the human lifespan. While the usual age of onset for Huntington's disease is in the late 30's to early 40's, there are as well juvenile cases with onsets beginning as early as age 4 and late onset cases that can only be detected in individuals in their early 60's. The new methodologies and new understanding about gene control, therefore, also presents an opportunity to investigate the basis for inter-and intra-family variations in ages of onset for Huntington's disease patients as well as for those who develop other genetic disorders throughout the lifespan.

Many of these disorders are manifest predominantly in the nervous system. Of the more than 1,600 currently reported genetically transmitted diseases, approximately one-third have a major effect in the nervous system. This reflects the large proportion of genetic information used in the development and functioning of the brain.

Neuropathologic studies at autopsy in patients with Huntington's disease provide evidence that this disorder depletes the brain of small neurons particularly in the basal ganglion and caudate nucleus regions. The molecular genetic evidence, on the other hand, was derived from the chromosomes in the white cells, the lymphocytes, of the blood. This information was reported by Dr. James Gusella at the Huntington's Disease Center Without Walls at the Massachusetts Institute of Technology and Harvard University and his collaborators in population genetics and neurology who identified a molecular marker on a specific chromosome, chromosome 4, tightly linked to the gene for Huntington's disease.

At the present time molecular marker studies in 16 large unrelated families with Huntington's disease have all shown that the gene for this disorder is located on chromosome 4, and that it is possible to use the observed molecular genetic patterns in family members to identify not only affected individuals but as well presymptomatic carriers of the gene who will develop this disorder sometime in their lifetime. This major advance in molecular genetics was based on a successful methodology to locate the gene for Huntington's disease on a particular chromosome, even though the investigators initially had no knowledge of where that would be. Furthermore, this approach provides an opportunity to search for the gene in the many other inherited disorders where the chromosome map location of the gene is unknown and where the gene products are unavailable for evaluation and potential therapy.

A presymptomatic service program for families with Huntington's disease is not yet offered in the United States because the scientific community wants to assure the reliability of the gene locus by conducting studies in a statistically appropriate number of large, unrelated, informative families. This portion of the research program should be completed shortly. The ethical issues encumbered in providing such definitive information on at risk individuals prior to any evidence of clinical illness has been an area of continuing discussions by both family members and the research community. Because of the long, ongoing relationships between members of the scientific community and members of the family organizations the ethical issues are being directly addressed. There are many obvious concerns.

One example is whether it is appropriate to provide testing and outcome information to all individuals who request it including those at risk individuals who are markedly depressed with a high potential towards self injury or suicide if the test results indicate that the person is a gene carrier. Who will be responsible for the long term care of such individuals? There is at present no treatment or cure for this devastating illness.

Molecular genetic studies with Huntington's disease as well as the procedures we employ in providing information and counseling to members of families with this disease will be the basis for the progression in our advancement with other genetically transmitted disorders where the gene locus is unknown and no treatment or cure is identified. In particular, Huntington's disease is the prototype for other late onset disorders with evidence of genetic transmission including Alzheimer's disease, familial amyotrophic lateral sclerosis, and stroke due to cardiovascular accidents (CVA).

For Huntington's disease the identification of a molecular linkage marker to the gene not only raises the immediate potential of a presymptomatic test for at risk family members but of eventually isolating the gene by utilizing other probes and restriction enzymes to overlap and span longer distances of DNA and `walk' to the gene. Now that the gene for Huntington's disease is located on chromosome 4, in a relatively short time it will be specifically localized by fine mapping procedures. It should then be possible to determine the nucleotide substitution(s) that results in the changed protein product at the basis of this disorder. Knowledge of the altered molecular structure should provide the basis for also determining the pathophysiology of Huntington's disease. The success of molecular genetic methodologies with Huntington's disease is in part due to the fact that its transmission is definitive as a completely penetrant autosomal dominant disorder. It provides a unique paradigm for investigation of many other genetic disorders and potentially those where the mode of transmission is problematic.

As noted by others, once methods become available to screen gene products, the determination of the genomic mutation and the mechanisms of expression responsible for the disease may provide the opportunity for rational gene therapy. An interesting and currently theoretical question is how to insert the normal functional gene into relevant tissue where it would act to correct the basic defect. At present no gene treatment for any human disease has been achieved, but this is the direction of modern medicine. Since population genetic studies have determined that all of us are carrying a minimum of 7 genes that negatively impact on our health and survival, it is most important that the national government support studies of methods to initially identify and in the long run control or cure the impact of the most deleterious of these disorders. The standard for positive health outcomes is available with Huntington's disease, and I urge your support through a continued high level of funding for research investigations with this disorder.

STATEMENT OF JOHN DONNELLY, VICE PRESIDENT, NATIONAL MULTIPLE SCLEROSIS SOCIETY

Senator WEICKER. The next witness is John Donnelly, vice president of the National Multiple Sclerosis Society. Please come right up and sit down, Mr. Donnelly. I want to reemphasize that it is necessary that we stick to the 5-minute time limit. I repeat, we have an awful lot of witnesses that have to be heard, and as most of you know, a matter which all of you are interested in is the budget resolution on the Senate floor.

My time is required there right now doing the very things that you are asking to be done, and I am going to have to insist that we do maintain that 5-minute time limit, both to accommodate your fellow witnesses and to accommodate the schedule of the floor, where I have got to go to present the case for the very things that you are speaking for here today.

This is not directed at you, Mr. Donnelly; it is a comment generally. I will tell you, I feel badly because of all the hearings that I attend. I learn more at these public hearings, and I enjoy hearing all of you more than I do all the professionals and the people in the administration, whatever, that come here and ramble on for hours at end. This, to me, is the real voice of what is going on. So please don't take it as a fact that I am bored. I am not. I could sit here all day long. That part doesn't bother me, but we do have other witnesses.

Mr. DONNELLY. I am John Donnelly, vice president for the National Multiple Sclerosis Society. You have heard eloquent and informed testimony about the need for a well-balanced NIH program including grants, training, clinical trials and intramural research. You have also heard of the need to provide funds for construction and renovation and equipment and instrumentation to maintain our preeminent research infrastructure.

Rather than to repeat these in detail, I would like to devote my allotted time to the economic argument for biomedical research. As you know, we are currently spending $1 billion a day on our health care delivery systems, or about 11 percent of the gross national product [GNP].

That we spend heavily on health is not at issue. Whether we spend wisely is. One of the biggest problems with our present health care system is that it focuses on treatment rather than prevention. Only 3 percent of the total health dollar outlay is earmarked for the scientist at the bench. Yet it is basic research that provides the biggest payoffs.

The virtual elimination in this century of dread diseases like polio, tuberculosis, diptheria, smallpox, and measles has saved the country untold millions. Polio immunization and vaccines for measles, mumps, and rubella, for example, save us over $2 billion a year.

Medical research also offers an excellent return on taxpayer money. Studies show a $13 return for every $1 so invested by the Federal Government. Between 1900 and 1975, the benefits exceeded expenditures by $300 billion, adjusted for inflation.

There are, in addition, direct and indirect spinoffs. More than $40 billion is contributed annually to the GNP for medical discoveries used in nonhealth-related products, and medical research has already spawned more than 100 new high-technology companies.

Polls show that an overwhelming majority of Americans believe that Government funds for medical research should be increased by a sizable amount, even in this era of tight Federal budgets and soaring deficits. Public support would be even stronger if more people realized the economic benefits of better health.

To illustrate, consider, please, the dollar value to the economy if scientists were to crack the mystery of multiple sclerosis by finding its cause and a cure. According to a Wharton School of Business study, the lifetime cost of multiple sclerosis alone are at least $21 billion. That represents the combined costs of medical treatment, loss of income to a quarter of a million Americans with multiple sclerosis and their family.

Because multiple sclerosis is a lifetime disease—people rarely die from it—its economic consequences are much greater than for some of the so-called killer diseases. Solving the mystery of how this crippler of young adult attacks the central nervous system could save the taxpayers billions in Medicare, Medicaid, and SSDI payments.

It would also generate significant revenue to the Treasury by reducing the dependency, putting the disabled back to work and contributing to the economy. The sick are tax consumers. The healthy are tax producers. The $1 billion a day we now spend to care for the sick is the biggest single line item in the budget, bigger even than defense. We spend $2,000 per year per American for health care. By contrast, the annual investment in biomedical research is only $25 per person.

That doesn't make sense, not when one major breakthrough could save billions a year the first year and every year thereafter. For example, in 1982 alone, $7.7 billion was saved due to a reduced fatality rate for strokes.

Could the money be spent more effectively? The needs in neurosciences are hardly overstated. The authority for this is Congress itself.

In 1983, it sponsored the Tracor-Jitco report, a needs survey which recommended dramatic increases for the study of neurological and communicative disorders, a disease group that affects 42 million Americans and costs the country $114 billion a year.

So many breakthroughs are now in sight that we should be steaming ahead at full speed on the biomedical front. In fact, our laboratories are at least throttled down to one-third of their power. For lack of funding, two out of three research applications cannot be funded. One scientist's success in obtaining a grant comes at the expense of other equally talented researchers.

We live with the haunting knowledge that unfunded researchers may have been the Dr. Jonas Salk of multiple sclerosis or some other maiming disease.

There comes a time in history when the opportunities must be seized or forever lost. We are at such a juncture in the biosciences. We no longer need to tolerate the existence of previously intractable diseases that kill and cripple us.

The keys to solving many medical mysteries are almost at hand. Progress now depends more on the degree of commitment, the will of our people, and the decision of our leaders, which is the Congress of the United States.

PREPARED STATEMENT

Senator WEICKER. Thank you, sir. Your statement will be inserted in the record at this point in its entirety.

[The statement follows:]

STATEMENT OF JOHN DONNELLY

I am John Donnelly, vice president for the National Multiple Sclerosis Society. I thank the committee for the opportunity to testify on behalf of our 500,000 members.

You have heard eloquent and informed testimony about the need for a well-balanced NIH program including grants, training, clinical trials and intramural research. You have heard also of the need to provide funds for construction and renovation and equipment and instrumentation to maintain our preeminent research infrastructure.

Rather than repeat these needs in detail, I would like to devote my allotted time to the economic argument for biomedical research.

As you know, we currently are spending a billion dollars a day on our health-care delivery system -- around 11 percent of the GNP. That we spend heavily on health is not at issue. Whether we spend wisely is. One of the biggest problems with our present health care system is that it focuses on treatment rather than prevention. Only three percent of the total health dollar outlay is earmarked for the scientist at the bench. Yet is basic research that provides the big payoffs.

The virtual elimination in this century of such dread diseases as polio, tuberculosis, diphthera, smallpox and measles has saved the country untold billions. Polio immunization and vaccines for measles, mumps and rubella, for example, save us over two billion dollars a year.

Medical research offers an excellent return on taxpayer money. Studies show a thirteen dollar return for every dollar so invested by the federal government. Between 1900 and 1975 the benefits exceeded expenditures by $300 billion, adjusted for inflation.

There are, in addition, direct and indirect spinoffs. More than $40 billion is contributed annually to the GNP from medical discoveries used in non-health related products. And medical research has already spawned more than 100 new high-tech companies.

Polls show that an overwhelming majority of Americans believe that government funds for medical research should be increased by a sizable amount -- even in this era of tight federal budgets and soaring deficits. Public support would be even stronger if more people realized the economic benefits of better health. To illustrate, consider the dollar value to the economy if scientists were to crack the mystery of multiple sclerosis by finding its cause and a cure. According to a Wharton School of Business study, the lifetime costs of MS alone are at least $21 billion. That represents the combined cost of medical treatment and loss of income to the quarter of a million Americans with MS and their families.

Because multiple sclerosis is a "lifetime" disease -- people rarely die from it -- its economic consequences are much greater than for some of the so-called killer diseases. Solving the mystery of how this cruel crippler of young adults attacks the central nervous system would save the taxpayers billions in Medicare, Medicaid and SSDI payments. It would also generate significant additional revenue for the Treasury by reducing dependency, putting the disabled back to work and contributing to the economy. The sick are tax consumers; the healthy are tax producers.

The billion dollars a day we now spend to care for the sick is the biggest single line item in the federal budget. Bigger even than defense. We spend $2,000 a year per American for health care. By contrast the annual federal investment in biomedical reserach is only $25 per person.

That doesn't make sense. Not when one major breakthrough could save billions a year -- the first year and every year thereafter. For example, in 1982 alone, $7.7 billion was saved due to a reduced fatality rate for strokes.

Could more money be spent effectively? The needs in neurosciences are hardly overstated. The authority for this assertion is Congress itself. In late 1983 the Tracor-Jitco Report, a needs-survey commissioned by the Senate Appropriations Committee recommended dramatic increases for the study of neurological and communicative disorders, a disease group that affects 42 million Americans and costs the country $114 billion a year.

So many potential breakthroughs are now in sight that we should be steaming ahead at full speed on the biomedical front. In fact, however, our laboratories are throttled down to one-third power. For lack of funding, two of three NIH research applications judged highly meritorious by a rigorous peer-review procedure are going unfunded. One scientist's success in obtaining a grant comes at the expense of other equally talented researchers. In this environment we live with the haunting knowledge that one of those unfunded researchers may have been the Dr. Jonas Salk of MS or some other maiming disease.

As a result of funding insufficiencies many of our brightest young scientists and doctors are leaving government and academic research institutions for industry and private medical practice. This flight will have serious long-term implications for basic research if allowed to continue.

There comes a time in history when opportunities must be seized or forever lost. We are at such a juncture in the biosciences. We no longer need to tolerate the existence of previously intractable diseases that kill and cripple us. The keys to solving many medical mysteries are almost at hand. Progress now depends more on the degree of our commitment, the will of our people and the vision of our leaders -- the Congress of the United States.

Thank you.

STATEMENT OF BARBARA DE LOUISE, PRESIDENT, GREATER WASHINGTON CHAPTER, ALZHEIMER'S DISEASE AND RELATED DISORDERS

Senator WEICKER. Next we have Barbara DeLouise, president of Greater Washington Chapter of Alzheimer's Disease and Related Disorders.

Senator WEICKER. Go ahead.

Ms. DELOUISE. Mr. Chairman, I want to thank you for this opportunity to speak for the Alzheimer's Disease Association. In the way of background, our chapter was first established in 1979 and, like our counterparts and 144 chapters across the country, our primary mission is to help support and assist those families that are struggling to cope with Alzheimer's disease.

Mr. Chairman, the first time that Alzheimer's disease was addressed at the national level came as a result of actions taken by this subcommittee back in 1981. At that time, my predecessor testified that Government had for too long ignored this terrible disease and the tremendous physical, emotional, and financial hardships it creates.

Since then, her burden has been lifted and the torment she described as an endless funeral has ceased. Unfortunately, for the families of more than 2½ million Americans, the struggle for Alzheimer's disease continues.

Nevertheless, I want to thank you and your distinguished colleagues for your leadership and support in the battle to conquer this terrible disease and thank you, as well, for the added measure of hope we have given those who, until recently, had no reason to hope.

At this subcommittee's insistence, the level of research support has steadily increased. This has led to a tenfold increase in the number of scientists studying this disease, but most importantly, what you have done is to lay the groundwork for some very promising new research. As Dr. William, the head of the Aging Institute recently testified, progress is being made on many fronts.

Most recently, for example, scientists have begun to suspect that the symptoms of Alzheimer's disease can be associated with the loss of specific populations of brain cells. This suggests that relatively normal brain function might be restored if the damaged brain areas could somehow be compensated for or replaced.

Still, Mr. Chairman, there is much to learn before we have a cure or an adequate treatment for Alzheimer's. That is why we are here again this year asking that you continue your support for basic medical research in this area. Specifically, we urge you to provide a minimum of $75 million to support research at the National Institutes of Health and the National Institutes of Mental Health.

We also ask that you provide an additional $2 million needed to support the 10 research centers that are now in operation, and although we know that this is a difficult year, we hope that you will weigh the long-term benefits of establishing the two new centers.

Mr. Chairman, as I indicated earlier, our chapter's mission is to work with the families that are confronting the day-to-day struggle associated with caring for an Alzheimer's victim, many of them at home. While science looks to the future for a treatment and a cure, we are working to ease the burden that is placed on families and care givers.

But peer support is not enough. Families and Alzheimer's victims are in desperate need of a wide range of services, including respite care, adult day care, transportation, administrative and legal assistance, insurance coverage, and in-home personal and medical services.

As you know, neither Medicare nor most private insurance plans cover Alzheimer's disease. What little help Medicaid offers comes only after the family resources are depleted. By that time, society has multiple victims on its hands: the patients and the family.

Under the circumstances, we ask that this subcommittee once again take a leadership role by directing the appropriate Federal agencies such as the Administration on Aging, to target greater resources in helping Alzheimer's families.

To conclude, we recognize that Government alone cannot eliminate the suffering caused by the disease but working together, through community-based groups such as ours and the Government at all levels, perhaps we can ease the burden on patients and their families until treatment or a cure is found.

PREPARED STATEMENT

For the record, Mr. Chairman, I would like to submit a copy of our national program to conquer Alzheimer's disease, and I want to thank you and your colleagues for supporting yesterday's budget resolution that adds a considerable amount to research for Alzheimer's and offers hope to us.

Senator WEICKER. Thank you very, very much. I appreciate your testimony.

[The statement follows:]

STATEMENT OF BARBARA DELOUISE

My name is Barbara DeLouise and I am Executive Director of the Greater Washington, D.C. Chapter of ADRDA, the Alzheimer's Disease and Related Disorders Association.

In the way of background, our chapter was first established back in 1980 and, like our counterparts in more than 140 chapters across this Nation, our primary mission is to help support and assist those unfortunate families that are struggling to cope with Alzheimer's disease.

Mr. Chairman, the first time that Alzheimer's disease was addressed at the national level came as a result of actions taken by this subcommittee, back in 1981. At that time, my predecessor testified that government had for too long ignored this horrible disease and the tremendous physical, emotional, and financial hardships it creates. Since then, her burden has been lifted and the torment she described as an endless funeral has ceased. Unfortunately, for the families of more than 2.5 Americans, the struggle with Alzheimer's disease continues.

Nevertheless, I want to thank you and your distinguished colleagues for your leadership and support in the battle to conquer this horrible disease. Thank you, as well, for the added measure of hope you have given those who, until recently, had no reason to hope.

At this subcommittee's insistence, the level of research support has steadily increased. This has led to a tenfold increase in the number of scientists studying this disease. But most importantly, what you have done is to lay the groundwork for some very promising new research. As Dr. Williams, the head of the Aging Institute recently testified, progress is being made on many fronts. Most recently, for example, scientists have begun to suspect that the symptoms of Alzheimer's disease can be associated with the loss of specific populations of brain cells. This could suggest that relatively normal brain function might be restored if the damaged brain areas could somehow be compensated for or replaced.

Still, Mr. Chairman, there is much to learn before we have a cure or adequate treatment for Alzheimer's. That is why we are here again this year asking that you continue to support basic medical research in this area. Specifically, we respectfully urge you to provide a minimum of $75 million to support research at NIH and NIMH. We also ask that you provide an additional $2 million needed to support the ten research centers that are now in operation. And although we know that this is a difficult year, we hope you will weigh the long term benefits of establishing two new centers.

Mr. Chairman, as I indicated earlier, our chapter's mission is to help families that are confronting the day-to-day struggle associated with caring for an Alzheimer's victim. While science looks to the future for a treatment and cure, we strive to ease the awesome burden that is placed on families and care givers.

But peer support is not enough, Mr. Chairman. Families and Alzheimer's victims are in desperate need of a wide range of services, including respite care, adult day care, transportation, administrative and legal assistance, insurance coverage, and in-home personal and medical services.

As you know, neither Medicare nor most private insurance plans cover Alzheimer's disease. And what little help Medicaid offers, comes only after family resources are all but depleted. By that time, the society has multiple victims on its hands--the patient and the family.

Under the circumstances, we ask that this subcommittee once again take a leadership role by directing the appropriate federal agencies, such as the Administration on Aging, to target greater resources on helping Alzheimer's families.

To conclude, we recognize that government alone cannot eliminate the suffering caused by Alzheimer's disease. But by working together--community-based groups such as our Greater Washington chapter, national ADRDA, and government at all levels--perhaps we can ease the burden on patients and their families until a treatment or cure is found.

For the record, Mr. Chairman, I would like to submit a copy of ADRDA's National Program to Conquer Alzheimer's Disease.

Thank you.

STATEMENT OF HON. JAMES ROOSEVELT, PRESIDENT, NATIONAL COMMITTEE FOR RESEARCH IN NEUROLOGICAL AND COMMUNICATIVE DISORDERS

ACCOMPANIED BY STANLEY VAN DEN NOORT, CHAIRMAN

Senator WEICKER. The next witness is the Honorable James Roosevelt, president, National Committee for Research in Neurological and Communicative Disorders.

Mr. ROOSEVELT. Thank you, Mr. Chairman. It is good to come back and see you in person.

Senator WEICKER. You are looking very fit. Service outside the Congress does you very well. It is an inspiration to all of us to get the hell out of here.

Mr. ROOSEVELT. I hope you won't do that.

Mr. Chairman, I have with me Dr. Stanley van den Noort. I would like permission to give him part of my time. As you know, I have been before this committee for some time now on behalf of the National Committee for Research in Neurological and Communicative Disorders, of which I have been president.

I would like to be candid with you and say that I appreciate the great, tremendous pressures which are on you fiscally at this time, but in spite of that, I think that I would like to emphasize that there is probably no area which is more deserving of being supported and to move forward than this particular area, first of all, for the work that is being done and the importance of it; second, the fact that it is so near resolution in so many different areas and that it would be tragic to have these stopped. For some of them, it would be irreversible.

It would to lose for a long time the gains we have been making in the area.

Mr. Chairman, if I may, in order to be more knowledgeable, because he is an expert where I am not an expert, I would like to introduce my friend and colleague, Dr. van den Noort, who is professor of neurology at the University of California. Irvine, and chairman of the National Committee for Research, and I am sure he will explain the urgent need for adequate funding for supported research.

Senator WEICKER. Thank you very much, Dr. van den Noort.

Dr. VAN DEN NOORT. It is an honor to appear before you. Your committee has demonstrated the importance of funding for neurological research by significantly increasing appropriations for the National Institutes of Neurological and Communicative Disorders and Stroke over the last few years. This momentum has generated support from the neuroscience community.

However, recent events in the Gramm-Rudman-Hollings area and administrative efforts to rescind funds have created real concern. I am here today to urge you to continue to withstand the even greater pressure to cut biomedical research. As Mr. Roosevelt has stated, we cannot afford to retard progress in our efforts to find the cause and cure for some of our most dread diseases.

Under current proposals, including a 4.3-percent across-the-board reduction in Gramm-Rudman-Hollings reductions, the administration is asking for a funding level for NINCDS of $3,099,000,000. This would be done from your appropriation of $433 billion in 1986. This cannot happen without serious and irreversable results. I am told NINCDS without changes will be funding a little more than 20 percent of all approved grant applications. That means that 4¾ of all approved applications would go unfunded. This, in an area of research offering great promise, is very depressing. It is particularly depressing for young investigators who may leave the field and not return when we need them later.

Mr. Conte has introduced a resolution in the House declaring the decade beginning in 1986 and ended in 1996 as the decade of the brain, and this resolution calls attention to the Congress and to the Nation that this is an area of discovery which needs priority attention.

The brain is the most important organ in the body. When the brain is dead, we give the other organs to people with a functioning brain. The brain is hard to study. Its exquisite architecture is locked in a box which receives input from several senses and directs action and expressions, speech, posture, and movement.

The sciences for the study of the brain lag behind research in other organs. One cannot easily sample the brain as one can blood or biopsy a tumor. The architecture of the brain that is sampled may not come from the right area. Over the last several decades, we have made remarkable progress in our ability to understand how the brain and its connections work.

We have also seen a true revolutionary ability to image the brain. In most fields of research, we have problems with basic research which are lacking in our design of rational treatment. But astounding advances in neuroscience place us in a different position. The toll of brain disease is probably greater than that of any similar set of diseases.

Several years ago, the Senate authorized a study which recommended a doubling of our investment in the NINDCS. I applaud that study but recognize it cannot be achieved.

We recommend this year your consideration in the budget of an appropriation level of $553,646,000 for NINCDS for fiscal 1987. Please be assured that we are aware of the fiscal constraints under which you work. However, we have an obligation to the neurological and communicative science communities to urge you to sustain the momentum that exists. Thank you.

Senator WEICKER. Thank you both very much. A lot of times, I think the best lessons are learned from the individual experiences that we all have.

How many of us in this room has it occurred to, time and time again when either a relative or a friend or somebody we know is sick, you can have everything in this world, but if you don't have your health, you don't have much. It is the most important thing, and yet we are not saying that corporately. As a national body we don't say that.

Individually, we all say it all the time. Somehow, sooner or later, somebody is going to wake up to this fact, and we are going to put the money where it belongs in that sense. I am amazed at the ability of us to explain in that fashion individually but not when it comes to our national priorities.

PREPARED STATEMENT

Thank you very much. Good to have you here. We will insert your statement in the record at this point.

[The statement follows:]

STATEMENT OF JAMES ROOSEVELT

Mr. Chairman and members of the committee, it is once again my distinct pleasure and honor to appear before you today on behalf of the National Committee for Research [NCR] in Neurological and Communicative Disorders, of which I am president. As many of you know, I accepted this assignment because of the devastating impact that neurological diseases and disorders had on our society. Since I have been associated with NCR, I have learned that this field of biomedical research offers some of the most promising results that are calculated to significantly reduce the extreme economic burden that these diseases place on all of us.

I would be less than candid if I sat here and requested that you appropriate enough funds necessary to support all good neurological and communicative disorders research in light of the Federal deficit situation. Having sat in your seats for many years, I am fully aware of the pressures currently being applied to you.

However, I think it would be a financial error to in any way back away from the commitment that this committee has made to supporting biomedical research in neurological and communicative sciences.

I would like at this time to introduce to you my good friend and colleague, Dr. Stanley van den Noort, who is professor of neurology at the University of California and chairman of the National Committee for Research. Dr. van den Noort will explain the urgent need for continued adequate funding for NINCDS-supported research.

Upon completion of Dr. van den Noort's testimony, I will introduce to the committee the other witnesses on this panel.

STATEMENT OF J. KIFFIN PENRY, M.D., EPILEPSY FOUNDATION OF AMERICA, ASSOCIATE DEAN, BOWMAN GRAY SCHOOL OF MEDICINE

Senator WEICKER. Our next witness is Dr. Kiffin Penry of the Epilepsy Foundation of America, associate dean of the Bowman Gray School of Medicine.

Senator SPECTER. How are you, Mr. Chairman?

Senator WEICKER. Senator Specter, it is good to have you here.

Senator SPECTER. Nice to be here.

Dr. PENRY. Mr. Chairman, good morning. As senior vice president and chairman of the government affairs committee of the Epilepsy Foundation of America, I would like to express appreciation for this opportunity to appear before this subcommittee today.

I am particularly pleased to speak on the proposed budget for the National Institutes of Neurological and Communicative Disorders and Stroke where I worked for 13 years, the last 4 as Director of the Neurological Disorders Program and Chief of the Epilepsy Branch.

Since leaving NINCDS in 1979, I have served as associate dean for research development at the Bunker School of Medicine at Wake Forest

University. Before proceeding further, I would like to thank you, Mr. Chairman, for all of your efforts to ensure adequate funding for programs serving individuals with developmental disabilities.

While many of the 2 million Americans who have epilepsy are able to lead virtually normal lives, successful medical treatment still evades many. There remain over 600,000 people with only partial relief and 400,000 with virtually no relief. These statistics, however accurate, fail to convey the real dimension of the problems encountered by the individuals whose seizure disorder has yet to be controlled.

It is a terrible problem with intermittent loss of control and the impact upon society that does not understand what this means to the individual.

In the new and competing grants, the President's budget requests, which would enable NINCDS to award 538 new and competing grants, 17 percent fewer than the fiscal year 1986 appropriation level, would not only have a disastrous effect upon the neurological research, but more importantly, upon the quality of life experienced by millions of Americans who will suffer from this lack in the future.

The clinical research, with particular regard to the problem of epilepsy is very important. The Epilepsy Foundation recognizes the need to balance effort between basic and neurological research and targeted research that relates to clinical areas. Epilepsy presents a special problem for us.

The Epilepsy Foundation of America believes. Moreover, the clinical study of epilepsy and many other disorders remain severely underfunded. Between 1984 and 1986, for instance, funding for clinical research increased 29 percent compared to 39 percent for basic research.

This gap is very likely to widen as competition for funds increase and leave the patient totally out of anything that they can look forward to in the immediate future. Dr. Goldstein offered one explanation for this alarming trend during the House testimony last year, and I know that you are very familiar with this, but for epilepsy, this is a special problem, while many of the 2 million Americans who have epilepsy are able to.

This is the area where we have to come into what is happening. I want to explain to you, if I may, an example of what this means in terms of the clinical research. Right now, for example, there are two epilepsy centers that are funded which we must be able to look at, in Minnesota and Yale University. This is work that is immediately applied to epilepsy.

Therefore, this disparity between the basic and clinical research must go on with some application with the patients for epilepsy. Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you very much, Dr. Penry. Your statement in its entirety wil be inserted in the record at this point.

[The statement follows:]

Statement of J. Kiffin Penry

Good morning. My name is J. Kiffin Penry. As Senior Vice President and Chairman of the Government Affairs Committee of the Epilepsy Foundation of America, I would like to express appreciation for this opportunity to appear before the Subcommittee today.

Epilepsy remains one of the most misunderstood health conditions. While there have been significant medical advances in the understanding and treatment of epilepsy during the past decade, half of those with epilepsy still cannot gain full control of their seizures. Normal one minute, out of control the next; children and adults with epilepsy are disabled not only by the unpredictable and devastating character of the disorder, but also by the constant misunderstanding and rejection by a society which fears what it does not understand.

While many of the 2 million Americans who have epilepsy are able to lead virtually normal lives, successful medical treatment still eludes many. There remain some 600,000 people with only partial relief from seizures, and 400,000 with virtually no relief. These statistics, however accurate, fail to convey the real dimension of the problems encountered by the individual whose seizure disorder has yet to be controlled.

The Administration's budget request of $399.351 million for the National Institute for Neurological and Communicative Disorders and Stroke (NINCDS) would not only have a deleterious effect upon all neurological research, but more importantly, upon the quality of life experienced by millions of Americans well into the future.

New and Competing Grants

The President's budget request would enable NINCDS to award 538 new and competing grants - 107 or 17 percent fewer than the FY 1986 appropriation level. The proposed funding level of $80.126 million is 24 percent less. In 1985, the priority score payline for NINCDS was 157 and its award rate was 38 percent. The automatic payline for this is currently 140. The anticipated overall award rate will be 27 percent. If the President's 1987 request was enacted, the overall payline would drop to 140 and the award rate to 22.5 percent.

If equivalent reductions, as proposed for FY 1987, had been enacted during FY 1985, the most recent year for which data is available, then the 1985 priority score payline of 157 would have dropped to 149. The funding rate would have dropped from 38 percent to 29 percent. Applying this reduced payline to grants actually awarded during 1985, we found 121 grants totalling $42.8 million would not have been awarded in the following specific areas: Epilepsy (6), Stroke (6), Multiple Sclerosis (6), Spinal Cord and Head Injuries (8), Parkinson's (5), Basic neurosciences (29), communicative disorders (35) and 26 in other neurological disorders.

CLINICAL RESEARCH

EFA believes clinical research in epilepsy and many other disorders remains severely underfunded. Dr. Goldstein testified during last year's House hearing that:

> "In order to make a meaningful breakthrough in the amount of support in a field like epilepsy, which is heavily based on clinical science as differentiated from basic science at the cell biologic level, it means that we must have a team of clinical investigators working with epileptic patients... It is that area of clinical research, dealing with the epileptic animal model or the epileptic human, which in the competition for available funds on a scientific merit basis does not receive the highest grades. This is true because these are the most difficult experiments to do, as opposed to a test tube experiment".

This fact is documented in the budget justification. Clinical research funding increased 29 percent between 1984 and 1986 compared to 39 percent for basic research. This gap is only likely to widen as competition for funding grows more intense.

Research and Development Contracts

The contract mechanism is often used to support high priority clinical research. This, unfortunately, is not the case within NINCDS today. The use of contract funding by NINCDS has steadily declined in recent years. The fiscal year 1987 request of $11.5 million is 32 percent less than the $15.2 million appropriated in fiscal year 1984. As a percent of the total NINCDS budget, contract funds have declined from 4.5 percent in 1984 to 2.9 percent in the 1987 budget request. Under the Administration's request, the overall NIH average, in comparison, would be 6.8 percent.

The Epilepsy Foundation is particularly concerned with the declining use of contract funding to support clinical research initiatives. Contract funds are used by the Epilepsy Branch of NINCDS to support the Antiepileptic Drug Development (ADD) program. Over the past decade, the Epilepsy Branch has evaluated and supported clinical research which ultimately led to FDA approval of four new drugs.

Epilepsy is a complex condition comprising more than 20 distinct seizure types. Facts show that 50 percent of all people with epilepsy or approximately 1 million individuals continue to suffer from occasional seizures, and over 200,000 people experience more than one seizure each month. Although more than a dozen drugs are available to treat epilepsy, most produce side effects which can impair an individual's normal abilities. For example, prolonged use of phenobarbital can result in slower physical and mental reflexes, which with continued use may lead to impaired mental functioning. Children and adults with epilepsy, sometimes become so sedated by the drugs they must take to achieve seizure control that ultimately they cannot function normally in school or on the job. In order to improve the lives of these individuals who pay a high price for seizure control, new and approved anti-convulsants must be discovered.

Dr. Goldstein, in response to a question asked during this year's hearing by Congressman Early, stated he would consider terminating the Antiepileptic Drug Development program as well as the Neuroprosthesis program if contract funding continues to decline. The Epilepsy Foundation views this possibility with great alarm.

Clinical Trials

A similar crisis confronts all of NIH. The President's budget proposes initiating only 9 major clinical trials during fiscal year 1987 compared to the 44 funded by this year's appropriation.

In response to a question which you asked, Mr. Chairman, Dr. Goldstein explained that the President's budget request would not enable NINCDS to initiate any major clinical trials next year. There are several promising anti-convulsant compounds which are ready for clinicial testing during fiscal 1987. The President's proposal to not initiate any new clinical trials is simply inexcusable.

Comprehensive/Specialized Research Centers

The importance and contributions of multidisciplinary centers in neurological research areas has long been documented. The Epilepsy Foundation recognizes the need to balance support between basic neurological research and more targeted basic and clinical research. We do not, however, believe such a balance exists today in epilepsy.

While the Administration's $26.4 million request for research centers represents a 12.5 percent reduction from the fiscal year 1986 appropriation, NINCDS plans to continue supporting 38 centers. The requested funds will require negotiated reductions of approximately 14 percent according to the 1987 Justification Document.

EFA believes there remains a strong need for an expanded multidisciplinary approach to epilepsy research. High quality, state of the art clinical research is needed. Effective methods of technology transfer between the laboratory and the practicing physician are needed. And there is an urgent requirement to train the clinician scientists of tomorrow if the momentum of epilepsy research is to be sustained.

Epilepsy Research Trends

The Foundation has used this occasion in recent years to express our continuing concern with the declining share of the research budget of NINCDS which is allocated to epilepsy research. Total NINCDS funding increased by 124% between 1978 and 1985 compared to a 58% increase for epilepsy research. Adjusting for inflation, epilepsy research funding increased less than 1% while the NINCDS budget increased 42% since 1978.

There can be no question that the epilepsy research field is ripe for further development. New antiepileptic drugs are awaiting the clinical testing phase. Side effects of existing drugs are being recognized. The potential of MRI, PET, MEG and other imaging techniques is very promising both in basic and clinical research. There is exciting new work being done in genetics that has the potential for application to epilepsy, especially at the molecular level. New applications of surgical techniques offer the possibility of therapeutic advances.

Yet Dr. Goldstein explained last year before the House Subcommittee that, "In order to make a meaningful breakthrough in the amount of support in a field like epilepsy, in addition to the fact that we need more and better trained investigators, we would have to increase the quantity of our support going into clinical research".

Many of the most important and successful advances in epilepsy research, diagnosis and treatment have come about because of the six Comprehensive Epilepsy Programs which were funded through the use of the contract mechanism during the seventies. Yet we have already noted that NINCDS funding of clinical research, comprehensive centers and research and development contracts have steadily declined.

This year, for instance, the University of Minnesota's Comprehensive Epilepsy Program - one of the original six CEP's - faces the lost of its research funding in July. Why? Because its priority score of 147 is slightly above the existing automatic payline of 140. Yet this multidisciplinary program project is considered one of the best centers in the nation. Its priority score is excellent for a major program project which has a significant clinical base.

Congress and NIH must find a new mechanism to evaluate clinical research grants so that clinical applications do not compete directly against basic grant applications. In doing so, Congress would begin to address the underlying problem presented by the funding situation faced by this center and other comprehensive centers or program projects.

Conclusion

Epilepsy is a prime example of a medical condition in which the individual and family members incur repeated direct and indirect costs. While some persons with epilepsy and their families are able to shoulder this burden themselves, society absorbs much of the cost in order to sustain and support individuals who have not been able to attain economic independence due to the seriousness of their condition.

NINCDS accomplishments have enabled countless individuals with neurological conditions to lead productive, independent lives. In order to continue this progress, the appropriation for NINCDS must be increased. The Administration's budget request of $399 million is both unwise and unacceptable.

The Epilepsy Foundation of America, joins with the Consortium for Citizens with Developmental Disabilities, in recommending a fiscal 1987 appropriation of at least $505 million. This amount would enable NINCDS to maintain its programs at approximately the 1985 level.

STATEMENT OF JEROME C. GOLDSTEIN, M.D., EXECUTIVE VICE PRESIDENT, AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

Senator WEICKER. Our next witness is Dr. Jerome C. Goldstein, the executive vice president of the American Academy of Otolaryngology-Head and Neck Surgery.

Dr. GOLDSTEIN. Mr. Chairman, members of the committee, staff, and guests, I am Jerome Goldstein, an otolaryngologist and executive vice president of the American Academy of Otolaryngology-Head and Neck Surgery. Otolaryngology is a hard word to say, spell, and understand.

Our specialty is concerned with surgery or cancer and other tumors of the head and neck, treatment for patients with loss of hearing imbalance, cosmetic facial surgery and treatment of allergic, sinus, voice, thyroid, and swallowing disorders. The academy has more than 8,000 active members, and annually, we handle more than some 45 million office visits and perform in excess of 7 million operative procedures.

A number of the residents now in training are planning clinical research careers. They are excited and eager to lengthen their training even beyond the required minimum of 5 years to become investigators. Can we keep their interest and enthusiasm when they see their mentors losing grants and constantly scrambling to keep important projects going despite cuts in funding or even abandoning clinical research altogether?

Budgetary actions taken now will have long-range consequences on these potential researchers and their patients. It is my purpose here today to speak on behalf of the 230 million citizens of the United States who have problems with hearing and 10 million additional who have problems with voice, speech, and language. I also speak for the 58,000 Americans who developed cancer of the head and neck last year and the 22,000 people who died from these tumors.

Our challenges here are multiple. Out of respect for your time, sir, I must refer you to my submitted written remarks or my detailed comments regarding these afflictions. Much scientific research relative to hearing and balance disorders is currently being supported by various institutes at the NIH.

Additional support is provided by the National Aeronautics and Space Administration, the Department of Defense, the National Science Foundation, and others. All of this work is in jeopardy, Mr. Chairman, if efforts to balance the budget come at the expense of this country's biomedical research effort. We must have strong NIH support, both to continue to make new scientific advances and to translate findings from research into clinical practice.

And we need a well-funded NIH in order to develop and maintain a pool of innovative clinician scientists. I know, sir, from the Weicker-Andrews amendment that you appreciate this. Many research areas are ripe for further exploration. Those that are particularly exciting relate to the immune system of the head and neck. Its understanding is essential for advancing our ability to effectively treat many cancers of the head and neck and to more effectively diagnose and treat those conditions which are referred to as allergies.

Insertion of electrodes into the cochlea offers the possibility of restoring hearing for some 2 million currently deaf citizens. Research into inner ear fluids will help those afflicted with various balance disorders. I wish to emphasize these are just a few of the areas of opportunity that we otolaryngologists hope and need to pursue.

In order to accomplish these broad goals and pursue these objectives, my academy strongly supports the recommendation of the ad hoc group for medical research funding and urges you to appropriate at least $6.09 billion for the NIH during fiscal year 1987.

This is the minimum funding level required if NIH is to sustain its current support of basic and applied research and research training. Specifically, in regard to the National Institute of Neurological and Communicative Disorders and Stroke, we recommend a level of $553,646,000. We believe this amount would ensure a basic maintenance of effort in these difficult times.

Finally, Mr. Chairman, I wish to express our academy's deep gratitude for all you have done over the years for biomedical research and especially for that which is has provided support in the area of neurological and communicative disorders. Thank you for this opportunity. I would be happy to answer any questions.

PREPARED STATEMENT

Senator WEICKER. Dr. Goldstein, thank you very much for your testimony. I greatly appreciate it.

[The statement follows:]

STATEMENT OF JEROME C. GOLDSTEIN

I am Jerome C. Goldstein, an otolaryngologist and Executive Vice President of the American Academy of Otolaryngology-Head and Neck Surgery. I appreciate this opportunity to appear before you to discuss the current status of research in the fields of head and neck medicine and surgery including disorders of human communication.

I am pleased to have the responsibility and privilege of representing the American Academy of Otolaryngology-Head and Neck Surgery. I know otolaryngology is a difficult word for many to pronounce and spell. We are the specialty concerned with medical treatment and surgery of the ear, nose, throat and related structures of the face and neck. This encompasses surgery for cancer and benign tumors of the head and neck treatment of patients with loss of hearing or balance, internal examination of the air and food passages, cosmetic facial reconstruction, and treatment of allergic, sinus, voice, thyroid, and swallowing disorders. The Academy has more than 8,000 active members including 96% of all board certified otolaryngologists and is the largest such organization in the world. Each year our members handle some 45 million office visits and perform in excess of 7 million operative procedures.

The training of an otolaryngologist is lengthy, because contemporary surgery and care of the head and neck requires thorough knowledge of some very complicated procedures. Otolaryngology requires a minimum of five years of specialized training after graduation from medical school. Twenty programs require 6 years of training. Currently there are 106 programs with 1,045 residents training to become otolaryngologists. A number of these residents are planning clinical research careers. They are excited and eager to lengthen their training even more to become investigators. Can we keep this interest and enthusiasm when they see their mentors losing grants and constantly scrambling to keep important projects going despite cuts in funding? A few of our experienced investigators have abandoned clinical research altogether. Actions taken in Fiscal year 1986 and proposed for Fiscal year 1987 will have long range consequences and could be responsible for a whole generation of patients enduring needless death and disability.

Historically, all physicians have been clinical investigators as well as health care providers, feeling their way slowly toward better interventions by trail and error and accumulated experience. This pattern has been fortified by the emergence of the science of medicine and as close associations developed between bench scientists, labs and clinics, our patients benefited.

This specialty of otolaryngology-head and neck surgery has been developing over a period of 150 years. In the early days, we were primarily the surgeons of infection, draining sinuses and ears to prevent the brain abcesses and death which in the before antibiotics era often resulted from mild upper respiratory infections. Today we use surgical microscopes to reconstruct or remove tiny parts of the ear and lasers to destroy tumors involving delicate structures within the voice box (the larynx) and the nose. We also apply the most sophisticated plastic surgical techniques of reconstruction to restore form and function to patients severely injured by birth defects, trauma or cancer surgery.

One of the very special features of Otolaryngology-head and neck surgery is that so much of what we do, and so much more that we could be doing if only we knew more, affects patients' ability to communicate. The physicians who practice our specialty deal with this daily. Speaking, listening, and understanding are incredibly complex phenomena which permit us to share our thoughts and feelings with those around us. These capacities are so basic to our lives that we take them for granted until or unless they are impaired in ourselves or someone we care about. Those suffering from communicative disorders are often condemened to second class citizenship. Bright children fail to learn; older persons become imprisoned in a world of silence and this in turn may result in severe depression, social withdrawal, and even mental illness.

It is my purpose here today to speak briefly on behalf of the 20 million citizens of the United States who have problems with hearing and 10 million additional who have problems with voice, speech, and language. At the present time these people need more from us than we, their physicians can provide.

I am also here to speak for the 58 thousand Americans who developed cancer of the head and neck last year. Although these tumors "only" represented some 5% of the new cancers diagnosed in 1985 and accounted for "only" 5% of the 450 thousand cancer deaths, that is more than 22 thousand people. At present, head and neck cancers are among the most debilitating of malignancies. Our challenges here are multiple. In attempts to improve the cure rate the treatment combinations of drugs, radiation, heating, freezing and surgery have become more aggressive. So have the challenges to restore form and function to minimize disfigurement. We must develop better methods for the early diagnosis and effective treatment and rehabilitation of these patients.

Cancer of the mouth and throat is virtually unknown among non-users of tobacco, Mister Chairman. Our Academy has been active and visible in its support to strengthen warning labels on tobacco products and to increase the federal excise tax on cigarettes to $.32 per pack. Two basic reasons for this tax increase are the significant data showing such increase would inhibit the number of teenagers undertaking this habit and ~~two, a~~ portion of the 8.8 billion dollars in additional revenue generated would hopefully be held in escrow to pay for some of the 22 billion dollars in smoking related health costs so that smokers, rather than non-smokers would be responsible for this bill generated by their habit. This was proposed by the honorable Edward R. Roybal, chairman of the select Committee on Aging in his "Smoking, Medicare/Medicaid, an Alternative Revenue Tax Act of 1985 (SMART)" which we understand was referred to the Committees on Energy and Commerce and Ways and Means where it still awaits action.

Much scientific research relevant to hearing and balance disorders is currently being supported by various institutes of the National Institutes of Health as shown in the report requested by your committee a year ago. Additional support is provided by the National Aeronautic and Space Administration, the Department of Defense, the National Science Foundation and other governmental agencies. All of this work is in jeopardy, Mr. Chairman if efforts to balance the budget come at the expense of this country's biomedical research effort as is currently projected. From our perspective, as physicians caring for patients with communicative disorders or cancer, it is obvious that too little of the brand new knowledge and technology that we all hear about has filtered down to our patients in the form of improved care. We must have strong NIH support both to continue to make new scientific advances and to translate more of the exciting findings from research laboratories into current medical and surgical practice. We need a well-funded NIH in order to develop and maintain the sizable group of innovative clinician scientists who can facilitate the technology transfer that must occur.

Many research areas are ripe for further exploitation. Those that are particularly exciting include the precise descriptive analysis of the immune systems of the head and neck region. This is essential for advancing our basic understanding for what is needed to cure many cancers of the head and neck, to control infections in this region, and to more effectively diagnose and treat those conditions commonly referred to as allergy. The identification of the genetic abnormalities which are the basis not only for some 50% of hearing loss and balance disorders but presumably some of the autoimmune disorders affecting the head and neck is exciting. Genetic counseling in the short term and the possibility of genetic manipulation hold out an important avenue of hope for our future citizens. I earlier commented on the crossing of the surgical frontier into the inner ear. The dramatic developments of insertion of electrodes into the cochlea, the cochlear implant, offers the possibility for restoring environmental contact to some two million profoundly deaf citizens who cannot be helped by standard means of amplafication. The research into inner ear fluid abnormalities offers hope to those afflicted with various types of balance disorders. I wish to emphasize that these are just a few of the critical areas of opportunity that we otolaryngologists-head and neck surgeons hope and need to pursue so that we may further improve the quality of the lengthning life span of our patients.

In order to accomplish these broad goals and pursue these objectives the American Academy of Otolaryngology-Head and Neck Surgery strongly supports the recommendation of the Ad Hoc Group for Medical Research Funding and urges you to appropriate at least $6.09 billion for the National Institutes of Health during fiscal year 1987. From our perspective as physicians this is a minimum funding level required if NIH is to sustain its current support of basic and applied research and research training. In fact, more NIH funding is needed to ensure that clinical applications of what we know can proceed at a rapid pace.

Specifically, in regard to the National Institute of Neurological and Communicative Disorders and Stroke, we recommend a level of $505 million. We have studied the budget pattern of this institute with care and believe this amount would ensure a basic maintenance of effort in these difficult times.

Finally, Mister Chairman I wish to express our Academy's deep gratitude for all you have done over the years for biomedical research and especially for that which has provided support in the area of neurological and communicative disorders. I will be pleased to hear any questions you may have.

Thank you.

STATEMENT OF BENNETT LAVENSTEIN, M.D., MEDICAL ADVISOR, TUBEROUS SCLEROSIS ASSOCIATION OF AMERICA

Senator WEICKER. The next witness is Dr. Bennett Lavenstein, the medical advisor of the Tuberous Sclerosis Association of America.

Dr. LAVENSTEIN. Mr. Chairman, good morning.

Thank you for the opportunity for being here. My name is Bennett Lavenstein. I am a pediatric neurologist at Georgetown University Hospital here in Washington and serve as a medical consultant to the American Tuberous Sclerosis Association.

On behalf of the association, I am happy to also represent their interests. Last year, Mr. Raymond Connors, who is president of this organization, our founding director, with a severely affected child, presented testimony to encourage the Congress and the United States through the efforts of your committee to recognize a disorder known as tuberous sclerosis, which is estimated to affect approximately 1 out of 5,000 to 1 out of 10,000 individuals on the basis of recent genetic studies.

It is also believed that many additional individuals with these disorders have manifestations. More importantly, highly affected individuals can pass on the severe form of this disease to their children. Genetic studies indicate that in the gene pool, that is, in genes that are passed from generation to generation, tuberous sclerosis represents a rather common, frequently transmitted potential disorder.

In past years, the organization has made specific requests to the committee directed toward tuberous sclerosis research and also to further understanding and publication of the nature of this disorder. A workshop was first held in 1984, which was at the national level and was attended by 140 persons.

Many scientists and clinicians participated in that workshop. Appended to my statement today is a list of some of the outstanding scientists who serve on the advisory board and represented major departments of neurological pediatrics and genetics from major universities from throughout the United States.

The workshop identified many areas of promising research but specifically addressed the fact that a new impetus would be necessary to outline the nature of the disorder and to increase public awareness. Dr. H. Frederick Bowman of Harvard MIT Developmental Health and Dr. Oppenheimer, director of pediatrics, were directors. Research workshops have worked very arduous to try to establish groundwork for a national case registry.

In addition, they have worked to develop a multiproject research consortium. As a result of their efforts in the past 12 to 24 months, it appears many basic mechanisms which apply to the development of the disorder, such as tuberous sclerosis, a genetically developed brain disorder, may be related perhaps to other neurologic disorders.

At this time, to accomplish the goal which is sought, it appears that it is necessary to request funds on the order of $1.5 million to be distributed over the next several years to establish a multiproject research registry to identify individuals, families, and affected potential families with the disorder.

The establishment of a national case registry would be a major priority in the future understanding and clarification and illustration of the disease. The cost of initiating and running a viable registry program is estimated to be on the order of approximately $250,000 for the first year.

Following the establishment of a case registry, further projects in the clinical and basic science areas involving pathologists molecular biologists and biochemists could be undertaken. We have learned from the past that there is widespread interest in this disorder. We have also learned that due to the proliferation of new techniques in the neurosciences, including sophisticated scanning techniques involving the brain, many of which have been developed, obviously, with funds appropriated by this Congress through the NINCDS, that offset of this research in the basic neurosciences has direct application to disorder such as tuberous sclerosis, which encompass the symptoms of epilepsy and mental retardation.

It has been stated that the eighties may, in fact, may turn out to be the decade of the brain, and in terms of neurologic research, the advancement of knowledge into genetic disorders which directly affect the developing nervous system and account for significant morbidity throughout life would fall into a category of diseases that would also be under investigation.

In the past, representatives of the Tuberous Sclerosis Association have appeared before the committee to acquaint the members with this disorder. While there are many disorders at this time that are competing for the public ear and for the public will, in world populations. I would guess that tuberous sclerosis is a permanent disorder. We hope that the message brought to your committee by myself will serve as a part of the record to alert members of your committee to the additional burden which exists in this sphere of knowledge to understand this disorder which has been present for well over 100 years and efforts which can be directed toward appropriating funds in the budget for further illustration of the case and treatment, genetic counseling would be especially appreciated.

Thank you, again, Senator and members of the committee for letting us be heard.

PREPARED STATEMENTS

Senator WEICKER. Dr. Lavenstein, thank you for your testimony. I appreciate it. Your prepared statement in its entirety will be placed in the record at this point along with other statements submitted for the record on appropriations for the National Institute of Neurological and Communicative Disorders and Stroke.

[The statements follow:]

STATEMENT OF BENNETT LAVENSTEIN

My name is Dr. Bennett Lavenstein, Assistant Professor of Neurology and Pediatrics, Georgetown University School of Medicine, and Medical Consultant to the American Tuberous Sclerosis Association (ATSA).

We are very pleased to be here today and thank you for the opportunity to be heard. As you know, Tuberous Sclerosis is a serious inherited disorder that may result in severe mental retardation, epilepsy, multiple physical handicaps, tumors in any vital organ and characteristic skin abnormalities. Recent studies have indicated that the prevalence of TS is 1:5000--1:10,000. It is believed that many additional individuals have this disorder with minimal manifestations. Nevertheless, these mildly affected individuals can pass on a severe form of this disease to their children.

In past years, the ATSA has made specific requests to this Committee directed toward Tuberous Sclerosis research. We are here again to continue the momentum that has been established for Tuberous Sclerosis research.

The first Tuberous Sclerosis Research Workshop, which was held on April 13, 1984, and co-sponsored by NINCDS and ATSA, was enthusiastically received by approximately 140 attendees. Many other leading scientists and clinicians who were unable to attend in person have since requested copies of the proceedings of the Workshop.

The TS research community is excited about the Workshop for it has identified a number of promising research directions which are fully feasible at this point in time subject to available funding. Material from the Workshop is coming close to publication. The publication of that effort will provide new impetus to the researchers who were involved in the Workshop, as well as others (worldwide) who were unable to attend. Another benefit of such publication will be an increase in public awareness of Tuberous Sclerosis.

Following the Workshop, a letter was sent to leading investigators in Tuberous Sclerosis and related fields inviting them to participate as members of the ATSA Scientific Advisory Board. The Advisory Board will participate in an ongoing review and development of approaches to the diagnosis, management, treatment and prevention of this disease. The letter was enthusiastically received; we have attached a list of the members on this important Board.

Dr. H. Frederick Bowman of the Harvard-M.I.T. Division of Health Sciences & Technology and Dr. Edgar Y. Oppenheimer, Professor in Pediatrics and Neurology at Boston University School of Medicine, Co-Directors of the TS Research Workshop, have been working together to establish the groundwork for the national case registry and for the development of a multiproject consortium research application in the basic science of Tuberous Sclerosis.

It became very apparent during the recent Research Workshop that many of the basic scientific tools which are needed to carry out investigations of the basic mechanisms in TS are available and have already been applied to other neurological diseases. Our immediate goal therefor is to apply these existing techniques to TS.

In order to accomplish this goal, case material must be made readily available to the research scientists and to clinicians. In this regard, it was the consensus of the Workshop that the establishment of a nationwide Tuberous Sclerosis registry should be given highest priority.

We feel that a nationwide case registry should be established in conjunction with ATSA. The cost of initiating and running a viable TS case registry program is estimated to be approximately $250,000.00 for the first year. This cost includes correspondence with tens of thousands of physicians and health care providers who may be in contact with individuals with TS. Ethical concerns such as informed consent, confidentiality and access to the information in the case registry are being addressed.

Following the establishment of the case registry, Doctors Bowman and Oppenheimer plan to develop a multiproject consortium research application in order to facilitate the conduct of basic science research in TS. The multiproject application will include a Clinical Core which will serve to gather clinical specimens for study by the various basic science research investigators (pathologists, biochemists, cellular and molecular biologists and clinical and biochemical geneticists). The ATSA Scientific Advisory Board will be used as resource individuals in the development of the Clinical Core. This is the first step in gathering the prerequisite expertise for the multiproject consortium effort.

Investigators in the Clinical Core will make extensive use of the case registry to obtain clinical materials. Adequate facilities to coordinate the activities of the Clinical Core such as preserving and disseminating tissue specimens for evaluations are needed. A conservative estimate of the cost of mounting the multidisciplinary consortium, including the Clinical Core, is approximately $1,300,000 per annum. This funding would pay for the Clinical Core, as well as fund 6-8 separate basic science research projects.

The total amount of support which we feel is needed to set up a case registry and to effectively utilize and mobilize existing investigators conducting relevant research is 1½ to 2 million dollars per year.

We have learned from the research workshop that there is widespread interest in TS among scientific investigators of highest quality. We now exist in a unique point in time where there is both a developing momentum and a confluence of interest among investigators from different disciplines, health care providers and Members of Congress. We want to build on this momentum and continue our work.

The ATSA strongly recommends a budget increase over the annual rate of inflation to NIH/NINCDS. A budget increase over the annual rate of inflation would permit NINCDS to maintain its current research efforts while affording new and promising initiatives (like Tuberous Sclerosis) the opportunity to seek and gain funding through HHS/NIH/NINCDS.

In conclusion, we would like to remind this Committee that there are thousands of families throughout the United States coping with this tragic disease. The consequences for TS families are monumental---emotionally, physically, and financially. Emotionally, marriages are greatly stressed and often end in divorce; unaffected brothers and sisters are denied a normal family environment. The undiagnosed TS child is usually subjected to excessive child abuse, both physically and psychologically, by parents, family members, professionals, and peers who do not recognize that he/she is critically ill. Victims and their families have desperate unmet needs The physical demands of 24 hour a day in-home care for such children defies adequate description. Financially, the effect can be catastrophic.

The impact of Tuberous Sclerosis for the patient is devastating and it is life-long. TS patients require a wide variety of services, i.e. drug, physical, occupational and speech therapy, to name a few. Identified TS children that grow to adulthood seldom have the ability for self-support and/or self-care.

Clinical facilities that specialize in Tuberous Sclerosis care and treatment are non-existent.

If we are to help Tuberous Sclerosis this picture must change. Research is the only hope to resolve the enigma that is TS. Additionally, once initiated, meaningful research programs will have many positive fringe benefits, not the least of which is to offer hope to a desperate group of sick and afflicted Americans.

Again, we wish to thank this Committee for the opportunity to be heard on what we consider a most urgent concern. I would be happy to answer any questions.

SUMMARY

The following recommendations are requested by the American Tuberous Sclerosis Association (ATSA):

1. That a budget increase over the annual rate of inflation be allocated to NIH/NINCDS.
2. That a minimum of $250,000.00 be allocated for the establishment of a nationwide Tuberous Sclerosis registry.
3. That a minimum of 1.5 million dollars per annum be allocated for the development of a Tuberous Sclerosis Multiproject Consortium Research Application in order to facilitate the conduct of basic science research in TS.

4. That the American Tuberous Sclerosis Association (ATSA), when appropriate, be an active participant of any effort(s) initiated by this Committee on behalf of Tuberous Sclerosis.

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STATEMENT OF THE JOINT COUNCIL OF ALLERGY AND IMMUNOLOGY

MEMBERS OF THE COMMITTEE

I have six points to discuss with you in regards to the Appropriations for the National Institute of Health.

1. Balance of Research

Research and development in health is one of the five main points in today's testimony. Without adequate research, breakthroughs in diagnosis and the prevention and management of medical illnesses becomes fewer and far between. Witness the development of vaccines for dreaded diseases like polio, that cripples; tetanus and diptheria, that kill and cause heart damage respectively; and german measles, that cause abnormal fetal development. Without research and development, we would still be managing the chronically ill from these diseases in increased numbers, at substantial costs, rather than prevention, which has saved dollars for the government and the tax payers. Witness, if you will, the development of the laser beam that has changed laboratory procedures for measuring serum proteins from days to minutes. Once again, research and development reduced the long-term costs of diagnosing these diseases.

The numbers of the appropriate grants for the NIH must continue to grow at least similar to the rate in our past three years, where it has increased from 5,000 to 6,000 grants. We, in the field of allergy, immunology and asthma would support this level of appropriate grants. However, the program mechanisms of training, clinical trials, intramural research, construction and renovation at the NIH and at various centers for relaced immune disease programs (CIRID) must be supported as well. Only then, can proper staffing and management of the program be adequately done.

Point #2

Recent directors and actions by the NIH (Secretary) and OMB to reduce funding across the board seriously impinges upon the individual institutes to appropriately manage their own programs.

Each institute knows the priorities which they need and these were ascertained by input with advisory consults established by Congress. New actions of the Secretary and OMB contradict the authority of each institute. Efficiency by directives to centralize decisions such as across the board reductions can be very counter-productive. Directives also increase the levels of paperwork and "lines of checking" for decision making and control. This can only add to the overall costs of management, which should be allocated to research.

In tight budgets, people in consults should decide the priorities, and not one formula for all, which takes the flexibilty out of individual institute decisions.

We urge you to develop bill language, restoring this flexibility to the individual institutes. Very strong language was used last year, yet OMB, NIH and the Secretary's office completely ignored it.

Point #3 - Training

It takes five to seven years of hard work to develop minds that can carry on and develop the ideas of research. Interruption of any phase of this long-term investment will result in decreased output for research and development, with consequent increases in the long-term costs of disease management. Mixed signals of funding may lead to discouragement and reduction in this resource for future research needs. Without researchers, the discussion for funds in the NIH is irrelevant.

Point #4 - Equipment and Instrumentation

The need for proper equipment and instrumentation is the second most critical part for research. This is the most costly, but the technology explosions allow the research ideas to be possible. One not only deals with macrobiology of the body or the organ system, but in research today the answers seem to be an intricate working of the cell for the mirotubular structures that produce the energy systems to the cell walls that make immunity the basis of understanding many medical diseases. Obviously, proper equipment speeds up the research and produces results that lowers the cost of medical care. It allows a better understanding of how cells work, how medicines help and decreases misunderstandings regarding the disease entity.

Point #5 - Construction and Renovation

Construction and renovation is a scary topic simply because of the need which is estimated at $2 - $4 billion. Some points are evident however:

--It is not going to get any cheaper by not doing anything.

--Many of our facilities which were built in the 1950's and 1960's are slowing down our research progress as much as not having the equipment or trainees.

--Funding for this program is usually ignored by the authority question.

We would suggest that you do have the authorization under section 301. If not there, one can be created. We would recommend a program of $200 million in fiscal 1987 to get the process started. We would also recommend that there be an equal match of Federal to private dollars as a requirement for any project to prove the intent and need of those applying. This formula would mean that the $200 million federal investment would equate to $400 million, not to mention the tremendous numbers of both short and long-term jobs created.

These last few points raise the larger issue of our research infrastructure. What roads, ditches, dams, airports and bridges are to this country--grants, contracts, a strong intra-mural program at NIH, patient education, equipment and building are to the fabric of medical research. Thus balance and flexibilty are necessary.

Our investment in this area pays for itself many times over.

Point #6 - Education

Funding for public education and outreach programs cannot be ignored. An important step in prevention is to recognize the problem and learn the prevention techniques. A good example of this is tuberculosis control, where no other mechanism exists, except for environmental control and treatment of positive cases. Another good example is AIDS, where educating the public has substantially lowered the infectious rate. The third example is the asthma care training management program, where the most vulnerable are the children, who lose more school days because of allergies and asthma, than any other chronic illness. In this educational program, the rate of reduction of illness days, hospitalization and emergency room visits is already an established fact. Funding for the public information groups saves in the long run to markedly decrease the costs of health management.

We urge you to continue a strong medical research program and not fall to the whims of short term budget problems. At at time when we are spending $400 billion annually in this country on health costs, $6 to $7 billion for research is not at all out of line. The Ad Hoc's Group for Research should certainly be viewed as a minimum. In fact, we today are spending less on medical research as a percentage of Health care costs than we were in 1977. If we are to ever get a handle on these costs, we must develop education, prevention and effective treatment programs. The only way to do that is through medical research.

STATEMENT OF THE AMERICAN HEART ASSOCIATION

The American Heart Association is the only voluntary agency in the United States devoting all of its human and financial resources to one goal: the reduction of premature death and disability caused by heart attacks, stroke and other blood vessel diseases. In accomplishing this goal we work in partnership with several research, education and prevention programs whose goals are similar in nature. One of these programs is the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS). We are pleased to have the opportunity to provide you with our comments and funding recommendations for the NINCDS.

In addition, because of our concern regarding the use of animals in research and the President's proposed elimination of the Biomedical Research Support Grant (BRSG) program, we have included comments and recommendations with regard to the NIH's Division of Research Resources in this statement as well.

Cerebrovascular disease (stroke) is the third leading cause of death, behind heart attack and cancer, and the leading cause of long-term disability in the U.S. Approximately 500,000 individuals suffer a stroke each year; in 1983 over 156,400 individuals died of stroke. Survivors of stroke now number almost two million. These individuals often face years of severe physical and mental impairment, emotional distress and overwhelming medical expenses. It is for these reasons that stroke is generally viewed as the most devastating of all human disabilities. It is also one of the most costly as well -- each year stroke and its consequences cost the nation over $11.3 billion.

The NINCDS is the Federal focal point for all neurological research, including stroke. The Institute was established by P.L. 91-692 in 1950 and funded its first program projects and clinical research centers in stroke in 1961. Since the Institute's establishment, advances in the neurosciences have occurred at a rapid pace. Since 1950, the NINCDS has concentrated on establishing a well-trained cadre of basic and clinical sciences in the neurology field and the development of a new core of knowledge in the neurosciences. Based on these accomplishments, the Institute is now prepared to address exciting new areas of responsibility: the prevention of neurological disease and the restoration of brain function where damage has occurred.

This new emphasis by NINCDS holds much potential for further progress in the prevention and treatment of stroke. Much of the progress against stroke in the past fifteen years has come from the identification and treatment of the major risk factors for stroke -- high blood pressure, atherosclerosis, high red blood cell count and diabetes. Since 1972, the age-adjusted death rate for stroke has declined by 47.1 percent.

The NINCDS Stroke and Trauma program administers basic, applied and clinical research investigations, including multidisciplinary research centers, for cerebrovascular disease. The Stroke Program's primary areas of research and research training are as follows: cerebrovascular circulation (including stroke and vascular disorders and studies of prevalence, epidemiology, prevention, diagnosis, therapy and rehabilitation); degeneration and regeneration of damaged brain nerves; transplantation of tissue of the nervous system; and the study of positron emission tomography, nuclear magnetic resonance and other imaging techniques, including assessment of research techniques for their clinical and diagnostic potential. Significant advances in the stroke field have and will occur as a result of NINCDS funding:

- In a recent major international clinical trial scientists discovered that a widely-used neurosurgical procedure to direct blood past obstructed brain arteries in stroke victims is no more effective than other available medical therapies for preventing stroke. The potential for savings from this valuable finding are great -- it is estimated that this procedure costs an average of $15,000 and several thousand are performed in the United States each year.

- NINCDS is preparing to evaluate the effectiveness of another commonly-performed surgical procedure for the prevention of stroke -- the carotid endarterectomy.

- o In the area of brain repair in the case of stroke, Institute-supported research has discovered that return of normal function 7 - 9 months after a stroke is not entirely due to the effects of rehabilitation; the brain has actually worked to repair itself. Investigations are proceeding to learn how to influence this naturally-occurring process to enhance its effects on the brain earlier to perhaps minimize damage caused by stroke.

The AHA is concerned that the recent Gramm-Rudman cuts and the President's proposed budget cuts for FY 1987 will have a devastating impact on the ability of NINCDS to continue many of its promising stroke research programs.

The President has proposed a 3.7 percent reduction in the NINCDS budget for FY 1987. The impact of this proposed level of funding on grants awarded by the Institute is tremendous. In FY 1985, the Institute awarded 722 research grants; in FY 1986, the Institute awarded 645 grants; under the President's proposed budget, only 538 research grants could be awarded. The Institute projects that its award rate in FY 1987 would be approximately 22.5 percent -- the lowest in NINCDS history.

While the number of research centers proposed to be awarded by NINCDS under the President's FY 1987 budget would remain the same as it is in FY 1986 -- 38 -- the level of funding for the centers program has been reduced by 8.7 percent. Funding for research contracts would be reduced by 8 percent allowing for only 60 rather than 64 contracts to be funded. The research training program would be held at its FY 1986 level of $12.6 million and 598 trainees and the intramural research and the research management and support functions of NINCDS would be given minimal increases, 1 percent and .6 percent, respectively.

With regard to the Institute's support for stroke research, AHA had been encouraged in FY 1985 to see a stronger emphasis placed on this highly important area of need. In FY 1985 support for stroke research increased 11.3 percent over the FY 1984 level. In FY 1986, support for stroke research increased only 2.3 percent over the FY 1985 level. Under the President's proposed budget, stroke research support would be reduced by 1.1 percent in FY 1987.

At a time when research in the neurological sciences is producing such exciting findings and clearly is accelerating our ability to treat and even prevent the occurrences of such life-threatening and costly diseases such as stroke, AHA believes that it is unwise to propose decreases in funding that the very programs that will continue to have a downward impact on the incidence of stroke and its debilitating consequences.

When asked what diseases within the NINCDS mandate are ripe for intervention at this time, during his recent appearance before the House Labor-HHS-Education Appropriations Subcommittee, Dr. Murray Goldstein, Director of NINCDS indicated that stroke clearly fit into this category. The AHA fully endorses Dr. Goldstein's assessment of the status of stroke research and would therefore like to recommend an appropriation for the NINCDS in FY 1987 of $479.3 million. This level of funding constitutes a 10.6 percent increase above the FY 1986 Congressionally-appropriated level for NINCDS.

DIVISION OF RESEARCH RESOURCES

Laboratory Animal Sciences Program

The Laboratory Animal Sciences and Primate Research program (LASPR) housed in NIH's Division of Research Resources (DRR), is responsible for supporting research projects that enable scientists to obtain and use animals effectively in health-related research. This is accomplished through grants which provide base support for the overall resources and a broad spectrum of multicategorical types of biomedical research conducted in seven Regional Primate Research Centers. The LASPR program also supports diagnostic laboratories, research manpower development in laboratory animal sciences, research on special nonanimal biomedical models, the improvement of laboratory animal facilities and other activities which support the various NIH programs.

In addition, The program advises NIH in the development of guidelines for the human care and use of animals in research and on the use of biomedical models which may lead to decreased use research animals.

The President's budget includes $38.9 million for the LASPR program for FY 1987. This is an increase of only 2.9 percent over the FY 1986 adjusted appropriation level and 1.6 percent below the FY 1986 Congressional appropriation for this program. Each of the program components of the LASPR program -- primate research centers, laboratory animal sciences and biological models and materials development -- will receive a minimal increase under the President's budget, however the Program will be funding the same number of research center grants, animal facilities improvement grants, individual and institutional training grants and contracts as it did in FY 1986.

AHA strongly believes that the LASPR program deserves a high priority for funding in FY 1986. The President's budget proposals for the DRR's animal program are highly out of line with its current needs. At a time when the public and scientific investigators continue to be concerned about providing the best possible care to research animals, it is essential that sufficient funding be provided for each of the LASPR's grant mechanisms. Therefore, AHA recommends that DRR receive a 10.6 percent increase over the FY 1986 Congressionally-appropriate level, or $370.5 million, in FY 1987.

Animal facilities and properly trained animal medicine personnel are a necessary aspect of all biomedical research activities. Furthermore, proper facilities and healthy animals help to ensure reliable research results. Our recommended 10.6 percent increase in DRR funding will only begin to meet the need for improving the wide-spread deterioration that currently exists in a majority of the research animal facilities located at biomedical research institutions in the U.S.

Biomedical Research Support Grant (BRSG) Program

The BRSG program was authorized in 1960 and it provides institutions heavily engaged in health-related research with a pool of flexible funds to meet particular needs determined by individual institutions not normally met by other PHS project grants. Allocating research funds on site allow research institutions to balance intervals needs to make the most effective use of emerging research concepts, techniques and talent.

The President's FY 1987 budget includes no funds for the BRSG program. We urge the Subcommittee to reject the President's proposal to eliminate this program. Our recommended funding level for the DRR for FY 1987, $370.5 million, would allow for continuation of this most important program.

STATEMENT OF THE ALZHEIMER'S DISEASE AND RELATED DISORDERS ASSOCIATION

INTRODUCTION

Based on his study of the world's great civilizations, the historian Toynbee concluded that a society's quality and durability can best be measured "by the respect and care given its elderly citizens." That being the case, never before has the measure of this country's commitment to the elderly been so critically important.

The challenges ahead

The rapid increase in the elderly population has given rise to a host of medical, economic, and social challenges which, if left unanswered, threaten a hemorrhaging in our society. And nowhere are those challenges more evident or more threatening than for the families and loved ones of the more than 2.5 million persons now suffering from a deadly neurological disorder known as Alzheimer's disease.

A national association responds

From the time the Alzheimer's Disease and Related Disorders Association (ADRDA) was first created in late 1979, the families, care givers, health professionals, and scientists who make up the organization have strived to mount a national effort to combat this dread disease. That effort includes:

- RESEARCH aimed at finding the cause and cure for Alzheimer's disease
- EDUCATION of the general public, health professionals, and care givers
- CHAPTER formation of a nationwide family support network
- ADVOCACY of essentially-needed government assistance
- and PATIENT and FAMILY SERVICES

In furtherance of these goals, the ADRDA submits the following National Program intended to serve as a guide in helping to meet some of the challenges brought on by Alzheimer's disease.

The growing threat of Alzheimer's disease

Medical researchers have established that Alzheimer's disease, the most widespread form of dementia disorders, is not simply a part of the aging process -- as evidenced by the fact that many of its victims are in their forties and fifties. Yet for some reason the vast majority of Alzheimer's sufferers are elderly persons.

According to the U.S. Public Health Service, Alzheimer's disease affects at least one person in twenty between the ages of 65 and 75, and every fifth person over 80 years of age. It follows, therefore, that as the number of elderly persons grows society can expect to encounter a substantial increase in the incidence of Alzheimer's disease and related disorders.* Apart from causing widespread human suffering, the disease will then carry particularly severe social and economic implications, as families, health professionals, and institutions are strained far beyond their limits.

Of course, from a public health perspective there can be no doubt that Alzheimer's disease has already reached epidemic proportions.

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*Today, the elderly constitute about 11 percent of the total U.S. population. By the year 2030, the Bureau of the Census projects that 21 percent of the population, 64.5 million persons, will be age 65 and older. Nearly half of that total will be over age 75.

EXPANDING SUPPORT FOR MEDICAL RESEARCH

> "The tacit assumption in our society that everyone will eventually become "senile" must be put aside. The expected norm should be that of a vigorous, intellectually active aging process."
>
> --Dr. Robert Katzman
> Professor and Chair, Department
> of Neurosciences, University of
> California at San Diego

Eighty years have elapsed since a German neurologist named Alois Alzheimer first described the effects of a progressive fatal dementia on a 51-year old patient. But it is only in the past decade that the disease which bears his name has received major research attention. Since 1976, research funding provided through the National Institutes of Health has increased from $4 million to nearly $50 million annually. Over the same period, the number of scientists studying the disease in the U.S. has jumped at least tenfold.

With greater federal involvement and increased scientific interest have come promising new research findings. One of the major advances over the past decade was the discovery that Alzheimer's patients often suffer from certain biochemical abnormalities in the brain. Most strikingly, they lack an enzyme that helps produce an important chemical messenger, or neurotransmitter, involved in learning and memory. In other studies, scientists have discovered similarities in protein fragments found in the damaged areas of the brain and in the brain's blood vessels, suggesting that perhaps science is moving closer to finding the underlying cause of Alzheimer's disease.

More recently, scientists have begun to suspect that the symptoms of Alzheimer's disease can be associated with loss of specific populations of brain cells. This finding could suggest that relatively normal brain function might be restored if the function of the damaged brain areas could be compensated for or replaced.

But in spite of this remarkable progress, as one government publication describes it, a diagnosis of Alzheimer's disease "carries with it a sentence of eventual mental emptiness."

In other words, there is still much to be done. For while new knowledge is helping to reduce the degree of impairment of Alzheimer's victims, science is still unable to prevent the disease, cure it, or stop its progression. And although research funding has increased in recent years, the total spent on finding a cause or cure still amounts to less than one-tenth of one percent of the $32 billion spent annually to care for victims of Alzheimer's disease.

Recommendations:

* That federal support for research on Alzheimer's disease be assigned a high priority at the National Institute on Aging, the National Institute of Neurological and Communicative Disorders and Stroke, and the National Institute of Allergy and Infectious Diseases.

* That funding for research on Alzheimer's disease be increased to at least $75 million in fiscal year 1987.

STRENGTHENING ALZHEIMER'S DISEASE CENTERS

> "Full support of the Alzheimer's disease centers program is a crucial element in this war. In good conscience, we cannot recruit a cadre of scientific soldiers and send them into battle without the ammunition they need to keep fighting."
>
> --Dr. David Drachman, Professor
> and Chair of Neurology at
> the University of Massachusetts
> Medical School.

From a scientific standpoint, there are a number of issues surrounding Alzheimer's disease that must to be addressed, not the least of which is finding a clinical diagnostic procedure for identifying Alzheimer's patients. Recognizing that a mechanism was needed that would address several of these problems simultaneously, two years ago Congress and the President launched a new and innovative effort designed to complement the work being conducted by independent researchers.

Since 1984, ten Alzheimer's research centers have been established -- each having clinical demonstration units together with a staff of investigators drawn from various scientific disciplines. As required by Congress, the ten centers are administered by the National Institute on Aging, working in cooperation with the National Institute of Neurological and Communicative Disorders and Stroke, the National Institute of Mental Health, and the National Institute of Allergy and Infectious Diseases.

The ten existing centers have already begun to have a dramatic impact on the status of research into Alzheimer's disease. As a result of the centers program, for example, a network of over 100 scientists throughout the country have begun to work together, sharing ideas, knowledge, and resources. Among other things, the participating scientists have already begun to standardize the diagnostic instruments used in identifying Alzheimer's disease.

Unfortunately, budget cutbacks threaten to weaken the centers program and slow the pace of scientific advances -- at a time when promising research leads point to the need for a stronger commitment to this effort. Additional funding in the amount of $2 million is required simply to maintain the basic centers program. Beyond that, an additional $5 million would permit the ten centers to expand clinical data gathering activities and support work on new and emerging research leads.

Recommendations:

* That an additional $2 million be provided in fiscal year 1987 to more adequately support the activities of the ten existing research centers.

* That an additional $5 million be provided to expand both basic research projects and clinical activities.

* That an additional $2.2 million be appropriated to support the establishment of two new research centers.

PROVIDING FAMILY SUPPORT SERVICES

According to the National Center for Health Statistics, over eighty percent of all home care is provided to the chronically ill elderly by family members. For the families of Alzheimer's victims, this usually entails mobility assistance, personal care, and household assistance.

Apart from placing an enormous financial burden on families, meeting the extensive needs of an Alzheimer's victim often results in severe stress and family dysfunction, manifested as physical illness, anxiety, depression, and family conflict. This is due, in large part, to the fact that Alzheimer's disease usually runs an agonizingly slow course, lasting anywhere from five to twenty years. Recognition of this fact has led to the development of programs designed to help ease the burden on caregivers; foremost among these has been the development of an extensive family support network by the Alzheimer's Disease and Related Disorders Association.

But peer support is clearly not enough. Family caregivers are in desperate need of a wide range of services, including respite care, adult day care, transportation, administrative and legal assistance, and in-home personal and medical services.

Recommendations:

- That the federal government forge a partnership with state and local agencies to launch a nationwide effort to help meet the needs of families caring for Alzheimer's victims. In so doing, government agencies at all levels should draw upon the knowledge and expertise of the Alzheimer's Disease and Related Disorders Association.

- That the Administration on Aging be directed to support exemplary projects to serve as models for rendering family support services. To the extent feasible, this effort should be carried out through a partnership arrangement with national voluntary organizations, such as the Alzheimer's Disease and Related Disorders Association.

- That the federal government offer subsidized loans to public and private nonprofit institutions to finance the development of respite care programs and adult day care centers for Alzheimer's victims and their families.

- That the National Institute of Mental Health continue its research on the family stress problems related to the care of Alzheimer's victims.

MEETING THE COSTS OF LONG-TERM CARE

Long-term care is, of course, a growing national concern. In his most recent State of the Union Address to Congress, President Reagan focused attention on the fact that "devastating illness can destroy the financial security of a family."

Nowhere is that more evident than with families struggling to cope with Alzheimer's disease, for the nature of this illness is such that the long-term care needs of its victims most often arise at a time when the family's economic and social resources -- including savings, pensions, and other assets -- are dwindling. Furthermore, the care and treatment of Alzheimer's patients is deemed "custodial" and specifically excluded from coverage under Medicare and practically all private health insurance plans. Consequently, the catastrophic costs of caring for an Alzheimer's victim are borne almost entirely by their families. And while Medicaid offers some help, this program most often favors institutionalization -- and is available only after a family has exhausted nearly all of its resources. (Of course, all of these problems are more pronounced when victims have no family or loved ones to turn to for help and support.)

To further compound the problem, families of Alzheimer's victims frequently encounter difficulties in obtaining access to nursing home care, since many facilities prefer short-stay, Medicare or privately-insured patients.

Recommendations:

* Federal policies should be developed which stimulate a broader range of alternative programs and services. To this end, Medicare coverage should be extended to victims of Alzheimer's disease; the Secretary of HHS should be directed to authorize Medicare waivers and home health care for these individuals.

* Far more emphasis (and resources) should be devoted to health services research on alternative delivery systems. A major portion of this research ought to be focused on developing an intergrated continuum of care, including cost-effective strategies for expanding community-based care and in-home services.

* Federal statutes should expressly prohibit nursing homes from discriminating in the acceptance or refusal of individuals as patients on the grounds that those individuals are on Medicaid or are victims of Alzheimer's disease.

* Families and care givers should be allowed a tax deduction or refundable tax credit to help defray the added costs associated with caring for an Alzheimer's victim at home.

* Any federal and/or private initiative to address the need for catastrophic or chronic illness insurance should include coverage for victims of Alzheimer's disease.

ENSURING EQUITABLE TREATMENT UNDER FEDERAL DISABLILITY PROGRAMS

The Social Security Administration has national responsibilty for the administration of both the Social Security Disability program and the Supplemental Security Income (SSI) program. The former provides cash benefits to those disabled workers and their dependents who have contributed to the social security trust fund; the latter provides for a minimum income level for the needy aged, blind, and disabled who qualify because of financial need. Under both programs, the definition of disability is the same: "an inability to engage in any substantial gainful activity by reason of a medically determinable physical or mental impairment which can be expected to result in death or has lasted or can be expected to last for a continuous period of not less than 12 months." (The decision as to whether an applicant is disabled, as defined by law, is made by a special disability determination unit in each state.)

Although federal statutes do not preclude benefit payments to Alzheimer's victims, the guidelines used to determine eligibility are rather vague when it comes to this disease.

This, in turn, has led to wide variations from region to region, resulting in an uneven policy toward individuals who hold a rightful claim to benefits.

Recommendations:

- Federal regulations and guidelines used in evaluating disability claims should be amended to include specific reference to Alzheimer's disease and related disorders.
- A mechanism should be established whereby the most current scientific knowledge available to the National Institutes of Health is communicated to those responsible for overseeing and administering disability programs.
- Government agencies, working together with the medical and scientific community and ADRDA, should devise specific assessment tools for use by examining physicians.

ESTABLISHING A CONSISTENT POLICY FOR VETERANS WITH ALZHEIMER'S DISEASE

The Veterans' Administration currently has no uniform nationwide policy regarding the care of veterans with Alzheimer's disease. As a consequence, some victims of the disease are admitted for treatment at VA medical facilities, while others are denied admission or referred elsewhere. In other instances, patients are being forced to leave VA facilities, thereby disrupting their care and placing even greater strain on families.

Recommendations:

- The VA should develop a fair and consistent policy with respect to the care and treatment of Alzheimer's victims. That policy, in the form of written guidelines, should be distributed to VA installations throughout the country.
- Local VA facilities should be instructed to develop and implement screening, couseling, and treatment programs for veterans and their families.
- The eligibility requirements for veterans diagnosed as having Alzheimer's disease should be lowered to age 50.
- A portion of VA intermediate-care hospital beds, perhaps ten percent, should be set aside for the care of veterans suffering from Alzheimer's disease and related organic brain disorders.
- The VA should institute a system of enrollment and tracking to permit greater coordination of inpatient care and community-based services.
- Pilot studies and/or model projects undertaken by the VA should take into account the special needs of veterans suffering from Alzheimer's disease.

MEETING TRAINING AND EDUCATION NEEDS

> "To the extent that individuals can be trained to help themselves and contribute to society, they preserve their autonomy and morale and they free formal and informal providers for other productive activities."
>
> -Dr. Robert N. Butler
> Professor of Geriatrics,
> Mount Sinai School of
> Medicine

Despite a growing awareness of the extent and burden of dementias such as Alzheimer's disease, there still exists a serious shortage of trained personnel, including research investigators, hospital and nursing home staff, safety and transportation personnel, home health aides, and family members.

Recommendations:

* Greater emphasis should be placed on career development of faculty and research investigators. As part of this effort, NIH should (1) expand the number of National Research Service Awards in the field of neuroscience, with particular emphasis on Alzheimer's disease and (2) strengthen the training component of the specialized Alzheimer's research centers.

* Clinical training needs must be re-evaluated in light of new research findings. Specifically:

- New training curriculum must be developed which targets on treating persons with Alzheimer's disease; special attention should be paid to basic training (and continuing education) for clinical care providers

- The Secretary of HHS should institute special training programs aimed at nursing home personnel, home health aides, pathologists, medical examiners, safety and transportation personnel, and families.

* Special emphasis should also be placed on the needs of special populations, such as minorities and the frail elderly.

PROMOTING COORDINATION AND PUBLIC AWARENESS

The fundamental need exists for greater cooperation and coordination among the several research institutions, health care providers, and families now engaged in one facet or another of this national problem. Furthermore, greater public awareness is essential if society hopes to overcome the growing challenge of Alzheimer's disease.

Recommendations:

* A national advisory council should be established to help develop, encourage, and guide research on Alzheimer's

disease, as well as to serve as a mechanism for conveying new information and ideas to physicians, nurses, care givers, and family members. The council, with the full support of federal agencies, should promote collaborative efforts among those agencies, university research centers, pharmaceutical houses, and others throughout the medical and scientific community.

* The council, as well as key federal, state, and local agencies should utililize the knowledge and expertise of the Alzheimer's Disease and Related Disorders Association.

STATEMENT OF MARVIN O. KOLB, M.D., REPRESENTING THE AMERICAN ACADEMY OF PEDIATRICS

Senator WEICKER. The next witness I am going to take out of order, because Senator Andrews has another committee he has to attend. He wanted to be here at the time that Dr. Marvin Kolb from the American Academy of Pediatrics, chief of staff, St. Lukes Hospital, Fargo, ND, appeared. So I will very briefly skip into that area, which is the National Institute of Child, Health and Human Development, and hear from Dr. Kolb and Senator Andrews.

Senator ANDREWS. Thank you very much, Mr. Chairman. Dr. Kolb, it is very good to have you here. Let me point out, Mr. Chairman, that Dr. Kolb has appeared over the years regarding children's key health care issues, especially with an emphasis on child care immunization and preventive health care.

Just last month, I held a rural health forum in Bismarck, and I told you about that, Mr. Chairman. The incredible statistic that we found was that 16 other countries have lower infant mortality rates than the United States. Dr. Kolb helped me in setting up that hearing and the results from that hearing, of course, you and I are going to use in defending the amendments that we will carry to the floor to make sure that we can make the proper investment in lowering these startling statistics.

I want to express in open session my appreciation to Dr. Kolb, whose background and help have given me the statistical data to be able to carry on this fight in a much better way.

Thank you, Mr. Chairman.

Senator WEICKER. Thank you.

Dr. Kolb?

Dr. KOLB. Thank you, Senator Andrews. I appreciate your assistance and help with this, too. Mr. Chairman, I am Marvin Kolb, a pediatrician from Fargo, ND. I am chief of staff of pediatrics at St. Lukes Hospital. I am here today representing the American Academy of Pediatrics.

In a departure from the academy's usual request for specific funding levels of categorical programs, this year, I would like to focus our oral comments on a central theme, infant mortality and infant morbidity. We choose this for two specific reasons. I think one Senator Andrews just alluded to.

The United States ranks 16th among all nations in infant mortality, comparable to Singapore. This is, of course, a national disgrace for us. Second of all, the programs over which this committee has jurisdiction play a significant role in improving this rating. So I think the current climate regarding maternal health and child programs, which have been shown to be effective and economical, put mothers and children at risk.

The American children today do not have the same problems that children had 15 to 20 years ago. Today's children are poorer. One-fifth of the United States' children today live below the poverty line; 21 percent live in single family homes. Emergency rooms are becoming the major source of care for families who have lost Medicaid and don't have any private insurance. Really, care is fragmented for our Nation's children. They are suffering disproportionately in these times of fiscal cutbacks and program consolidation.

Basic problems persist, and they discredit us all. Using survival rates of newborns as an indicator of how well a society cares for its children, in this country, nearly 40,000 infants will die a year in their first year of life. Of these 40,000, roughly 70 percent die in the neonatal period, which is the first month of life.

More than two-thirds of these die of what is called low birth weight infants, infants weighing less than 5 pounds. Thusly, the low birth weight infants have a death rate 200 times greater than the normal infant. Unquestionably, the factors contributing to infant mortality and morbidity are complex and overlapping.

But solutions are within reach. Not all infants can be saved from death or disability, but many more could have a healthy life. There is going to be short-term and long-term strategies that Congress must institute if progress is going to be made. Many of these involve the obvious: Pregnant mothers must have adequate nutrition, further research must be provided, and children must be immunized. In short, all efforts to prevent avoidable deaths or disability among infants must be taken.

All programs impacting upon children play a role and all are important. Today, I would like to focus my attention really on two programs that merit attention and focus: First of all, the Federal Childhood Immunization Program, the most basic and successful preventive health program on Federal books. Vaccine prices due to insurance and liabilities continue to soar. In fact, the cost to immunize a child today has increased 500 percent in the last 4 years. Prices for 1987 may go up another 50 percent.

Fortunately, while the costs of immunization go up steeply, the budget for Federal childhood immunizations have not. One-half the children in this country depend on public programs for their immunization. At the present proposed budget level, one-third of these children may not get immunizations.

The academy urgently recommends that the Congress reinforce its support for the Federal Childhood Immunization Program. We simply cannot allow children to die of diseases that should never occur. We sure can't afford to treat these children for crippling conditions that are perfectly preventable.

As a pediatrician, I am active in the NICHD. They are involved in the prevention of diseases for the low birth weight. Another project of NICHD is a vaccine for children. Special attention must be directed to pertussis vaccine, as NICHD has promising research for pertussis. They are about to start field trials, but an additional $1 million is needed to continue these important trials.

I know how much even needs to be earmarked, but $1 million must be earmarked for this promising pertussis research. Once infancy is past, injuries, not disease, become the leading cause of death and disability. This is of particular interest for me and here again, prevention is of primary importance.

The NICHD prevention of injury processes was an exciting beginning. I cannot emphasize enough the directive to NICHD for them to continue and expand injury prevention work.

In conclusion, let me reemphasize that inferences must be drawn from our infant mortality rate which go beyond the immediate components of that measure. Changes in the measure of infant mortality and morbidity which can be sustained over time will not occur without diligent and continued attention to all major influences of the health of our population.

PREPARED STATEMENT

As a society, we simply cannot afford the wastage of human resources of our children and youth. As pediatricians, we feel it is incumbent upon us to present to you in this context the opportunities we share to shape healthy and productive adults.

I thank you for your time.

[The statement follows:]

STATEMENT OF MARVIN O. KOLB

Mr. Chairman, my name is Marvin O. Kolb, M.D., a pediatrician and Chief of Staff at St. Lukes Hospital in Fargo, North Dakota, here today representing the American Academy of Pediatrics. Members of the appropriations panel have been steadfast advocates for children over the years and I have every confidence that this commitment will continue.

It must. Crucial maternal and child health programs -- programs which are demonstrably effective and economical -- remain at risk in the current climate, as Congress weighs across-the-board cuts against more targeted savings for fiscal 1987. The case for careful assessment is powerful and can be captured concisely: INFANT MORTALITY AND MORBIDITY.

With more and more solid information available now on the vulnerabilities of children, especially babies, it is unimaginable that members of Congress would sharply diminish their support for federal initiatives which help address these serious maternal and child health problems. Indeed, after five years of belt-tightening, increased attention and bold innovation are all the more necessary.

American children today do not have the same problems as children had 15 or 20 years ago because they aren't the same kind of children. Today's children are poorer, relative to the rest of society, than children of the 1960s were. One-fifth of U.S. children live below the poverty line and 21 percent live in single-parent households. Emergency rooms are becoming the chief source of care for families who have lost Medicaid benefits and have no private health insurance. Hence, attempts to assist children are fragmented, sporadic and take place in the absence of an overall context or well-established sense of priorities. Consequently, children suffer disproportionately in times of fiscal cutbacks and program consolidation. It is important to appreciate the uncertain position of pediatric programs in 1986 because it is from here that we enter a new era of sweeping change in our health care system.

Basic problems persist, and they discredit us all. The survival rates of newborn infants serve as an indicator of how well a society cares for its most vulnerable members. Regrettably, our national infant mortality rate for 1984 was 10.6 deaths per 1000 live births, ranking the United States only 15th among nations having a population greater than 2 million. With approximately 3.6 million births in this country annually, nearly 40,000 infants will die during their first year of life.

Roughly 70 percent of these deaths occur during the neonatal period, the first 28 days of life. By far the greatest risk for neonatal death is among low birth weight (LBW) infants, those weighing less than 2500 grams (5.2 pounds). More than two-thirds of deaths in the neonatal period occur among LBW infants. The risk of neonatal death for LBW infants is 200 times higher than that for normal birth weight infants.

It is therefore of profound concern to the Academy that current national policy has been but marginally effective in reducing the proportion of LBW infants. The decrease in the incidence of LBW deliveries from 7.7 (per 1000) in 1960 to 6.8 in 1983 represents only a 14-percent decline. (Post neonatal mortality, deaths from 28 days to one year of age, accounts for the remaining 30 percent of infant deaths -- and fully 20 percent of these deaths occurs among former LBW infants. The remainder are related to environmental conditions and infectious diseases. Sudden Infant Death Syndrome accounts for 33 percent; infections, 10 percent; accidents, 7 percent.)

Unquestionably the factors contributing to infant mortality are complex and overlapping, but solutions are within reach. The answer to the dilemma, as complex as it may be, is a collaborative commitment by policy makers, health care professionals from a variety of disciplines and corporate and community leaders to make infant mortality and morbidity a priority deserving special attention and immediate action. Steps by both the public and private sector need to be taken. Not all infants can be saved from death or disability, but many more could have a healthy life.

There are short-term and ~~long~~-term strategies that leaders must institute if progress is to be made. And many of them involve the obvious, e.g., prenatal mothers must receive adequate nutrition; further research must be promoted; children must be immunized. In short, all efforts to prevent avoidable deaths or disabilities among infants must be taken.

Federal support for vital maternal and child health programs over the years cannot be underestimated -- Congress at least has helped limit problems associated with infant mortality. Still more needs to be done, however, and Gramm-Rudman must not be permitted to tighten the clamp on a funding squeeze already five years too old.

This testimony will focus on a variety of programs that influence infant mortality and morbidity in the United States directly or indirectly. The Academy will not -- cannot -- choose among them to help members of Congress apportion imprudent and improvident cuts. Mothers and children did not double the national debt since 1981, and given the lamentable level of infant mortality and morbidity, they cannot now be conscionably sacrificed at the altar of misplaced priorities. Each of the following areas of federal funding makes a special contribution to the ongoing battle against infant mortality and morbidity. Each is worthy of continued, even increased support. As are all American children.

IMMUNIZATIONS

The Federal Childhood Immunizations Program has been a remarkable success by any measure -- millions of dollars in funding cuts today could cost the nation hundreds ~~of millions~~ of dollars in health care expenses tomorrow.

But vaccine prices, owing substantially to insurance and liability costs, continue to soar. In fact, the price for vaccines to fully immunize a child has risen from $6 in 1982 to more than $30 today -- a 500-percent increase in four years. Prices in 1987 may rise another 50 percent. Unfortunately, while costs of immunization have gone up steeply, the budget for federal childhood immunizations has not. The number of children to whom the government can provide vaccine has declined by two-thirds. If the President's budget for 1987 were adopted by the Congress, states would be able to supply vaccine for still 400,000 fewer children.

As startling as these numbers are, they tell only part of the story. States, faced with skyrocketing vaccine costs, are being forced to lay off immunization workers, leaving clinics and medical-records work unstaffed. They are beginning to implement copayments for the poor, some as high as $15 per shot. And the President's budget proposes no funds for the yet incomplete vaccine stockpile, even though mere months ago we were forced to ration childhood vaccines in this country.

All of these problems are compounded by Gramm-Rudman. The first round of relatively shallow cuts eliminated funds for more than 65,000 children's shots. Every percentage point cut from 1987's budget will mean another 10,000 children without federal vaccinations. If present deficit forecasts are accurate, hundreds of thousands of children may be eliminated from the program.

The Academy urgently recommends that Congress reinforce its support for the Federal Childhood Immunization Program. We cannot allow children to die of diseases that should never occur, and we cannot afford to treat children for crippling conditions that are perfectly preventable.

NIH Research

The pediatric community is pleased to join with the 125 member organizations of the Ad Hoc Group for Medical Research Funding in support of a $6.079 billion appropriation for NIH for fiscal year 1987. Additional support for basic research rests on the premise that the long-term economic strength of this nation and the continued improvement in the well-being of its people demand a sustained investment in scientific research and in our investigators. While we recognize and applaud the attention given by the various institutes to the areas of maternal and child health, our comments will center on the National Institute of Child Health and Human Development (NICHD), the focal point of these critical efforts.

To stint funding for this Institute is untenable. Even during a time of shrinking budgets, it is shortsighted to decrease monies for the Institute directed at preventing disability and death during the critical period surrounding infancy and the ensuing childhood years. In the area of child health research we stand at an important crossroads where new medical opportunities exist. Through your leadership, let us be far-sighted enough as a nation to take advantage of these recent developments.

Among special emphasis at NICHD today, understandably, are expanded research activities in the prevention of low birth weight. The program includes increased research on intrauterine growth retardation (IUGR) and prevention of premature labor, the two factors responsible for low birth weight.

New vaccines for illnesses of infancy and childhood are another top priority. Whooping cough, typhoid fever and meningitis due to Hemophilus influenzae are still responsible for illness, death or permanent disability in many children. Special attention must be directed to pertussis vaccine. NICHD intramural scientists have recently isolated and purified the single component of the pertussis organisms which they believe is sufficient to produce an entirely safe and effective vaccine. Now they are about to start field trials of their new vaccine in Sweden, where without vaccine use pertussis has reached epidemic proportions. An additional $1 million must be targeted to continue these important trials.

Once infancy is past, injuries, not disease, become the leading cause of death and disability. Here again prevention is of paramount importance. Preventive approaches involve both pediatrics and the behavioral sciences. To expand this research, NICHD last year issued a special solicitation for research grant applications on behavioral approaches to injury prevention. More attention must be focused on this area.

Maternal and Child Health Block Grant

The MCH block on a lean budget continues to do important work through its component programs: Title V Maternal and Child Health/Crippled Children's Services; Lead-Based Paint Poisoning Prevention; Sudden Infant Death Syndrome; Supplemental Security Income Program for Disabled Children; Adolescent Pregnancy Services; Genetic Diseases Program; and Hemophilia Diagnosis and Treatment Centers. But increased support is necessary, especially if the Administration successfully caps federal funds for Medicaid.

Dramatic cost shifting from other health programs, cutbacks in needed services or both would occur. Experience tells us that children would bear an unfair share of this burden. With increased fiscal pressures on Medicaid, a growing number of young mothers and children may be forced to turn to the services provided by the maternal and child health block, services already stretched to capacity. At particular and growing risk are the "new" poor, who face a void in maternal and child health services.

Emergency Medical Services for Children

Nearly 18 million children receive emergency medical services annually with as much as 55 percent of all deaths up to age 15 due to injuries. Congress recognized the imperative need to improve emergency medical services to children when it authorized funds for demonstration programs for emergency medical services for childen as part of the Preventive Health Services Block. Although the Administration budget proposes to eliminate these programs, we believe a more haphazard approach could lead to longterm disabilities or deaths, an expensive price for society to bear by any definition.

Head Start

Research findings on the effects of early childhood education demonstrate increased school success, increased employment potential, reduction in dependence on public assistance, decreased criminal activity and positive effects for parents and families of children who attended preschool compared with children who had not. A $1 dollar investment in preschool education returns $4.75 in savings.

Head Start, owing to its comprehensive nature which incorporates health, nutrition, social services, education, parent involvement and services for special-needs children, is the most successful federal preschool program. The commitment of parents, staff and community to the Head Start program attests to its importance. The Academy believes that Head Start should continue to be funded at its current level.

Primary Care Training

In spite of the Administration's proclamation that health professions subsidies are no longer necessary and program termination imposes no cost to society, such is most certainly not the case for primary care education. The need for adequate support of pediatric primary care training grants, as supported through the Public Health Service, is pressing.

Primary care is the most comprehensive, cost-effective way of providing health care. Primary care reduces the occurrence and subsequent need for more expensive tertiary consultation and inpatient care. In fact, most primary care pediatricians see patients on an ambulatory basis.

In conclusion, let me reemphasize that inferences must be drawn from our infant mortality rate which go beyond the immediate components of the measure, i.e., death to infants under one year of age, which speak to risks, needs and services for infants, children and young families. While this statement stresses the medical and health components, many other programs influence infant mortality and morbidity and deserve your attention and support. These include Medicaid, WIC, Family Planning, AFDC, Child Abuse, Developmental Disabilities, Migrant and Rural Health, Indian Health and Child Care. All play a role. One cannot be sacrificed for another. Changes in the measure of infant mortality and morbidity which can be sustained over time will not occur without diligent and continued attention to these several major influences on the health of this population.

As a society, we simply cannot afford the wastage of human resources in childhood and adolescence. As pediatricians, we feel it is incumbent upon us to present to you in this context the opportunities we share to shape healthy and productive adults.

SUMMARY OF RECOMMENDATIONS
AMERICAN ACADEMY OF PEDIATRICS

($ in Thousands)

	FY 86 APPROPRIATION	FY 86 G-R-H REDUCTION	FY 87 PRESIDENT'S REQUEST	AAP REQUEST
1. Childhood Immunization Program	59,500	-2,500	56,000	98,000
2. Maternal and Child Health Block Grant	478,000	-20,554	478,000	478,000
3. National Institutes of Health	5,498,000	-236,414	4,936,000	6,079,000
National Institute of Child Health and Human Development	321,796	-13,838	309,119	376,745
4. Pediatric Emergency Medical Services	2,000	-0-	-0-	2,000
5. Primary Care Training Grants Internal Medicine/Pediatrics	18,500	-796	0	18,500
6. Head Start	1,087,000	-47,000	1,075,000	1,087,000

Senator WEICKER. Thank you very much, Dr. Kolb.

Senator Andrews?

Senator ANDREWS. Mr. Chairman, I think Dr. Kolb has made the precise statement that helps us so much in pointing out that even if you are so flinthearted that you don't like children, even if you hate your fellow human being, these are programs that should be supported because they are investment programs that will save dollar for dollar.

So if you only worship the dollar, the program that Dr. Kolb just outlined are programs that must be followed, because I would suspect it is a choice that for every dollar invested in childhood immunization, we are going to save $25 to $30 that we wouldn't have to spend later on taking care of the handicapped child. That is the question, and that is the statement, and that is what is going to help us in our Appropriations Committee's work.

I appreciate, Mr. Chairman, your having Dr. Kolb testify and your support. Might I point out that my fellow Congressman and a doctor for whom I have the utmost respect that the chairman for this committee is one of the great champions of what you espose, and he does it effectively and well. I am proud and pleased to be part of his effort.

Dr. KOLB. Thank you, sir.

Senator WEICKER. Thank you very much, Senator Andrews. There are two things I would like to comment on. First of all, I don't know if you are aware, but one of the clinical trials that has been canceled will not take place within the purview of the budget submitted by the President is the clinical trial on pertussis. That will not be funded this year. Senator Andrews and myself will try to see to it the funds go back in there, but just that type of clinical trial, some 44 clinical trials, indeed, in a variety of areas, are scheduled to be canceled.

I think that is a crime. That is an absolute crime, because as you are aware, and I say this not to you, but to the public as a whole, these clinical trials usually come at a stage of the proceedings where there is promise and something occurring that could relieve a particular condition or ailment.

This isn't just the beginning of the road. This is well down the road, and there are 44 of these clinical trials that are scheduled for cancellation. That is criminal.

Last, I have got a personal request, since you are here representing the American Academy of Pediatrics. I think the time has come; you know, it is fine for Senator Andrews, Senator Weicker, and Senator Burdick, also, others, to stand out on the floor of the Senate and argue for these matters that you speak of. And we do.

But clearly, we have been in the minority. Senator Burdick just entered the room. We are clearly in the minority.

Senator WEICKER. And we need help. We need help. Clearly, the Senate of the United States and the House of Representatives of the United States are going to reflect what it is the people of this Nation want. I think you have got a tremendous opportunity. Talk about a credibility factor, nobody in this room achieves the credibility that the family pediatrician does.

Dr. KOLB. Thank you, sir.

Senator WEICKER. I realize that philosophically, maybe, and partisonwise, a lot of your colleagues like Ronald Reagan. Fine. But that is not the issue. The issue is just as you phrase it here: the children of this Nation. I think it is time that you delivered that message to the families of this Nation. Let them get on the backs of the Congressmen and Senators. That is the fastest way to get something done around here.

I hope the American Academy of Pediatrics will move in that direction and not figure that they are free of their obligation after you testify. I wish they would say the same thing to every parent that walks into their offices.

Dr. KOLB. Thank you, sir.

Senator WEICKER. Senator Burdick?

Senator BURDICK. Thank you, Mr. Chairman, and welcome to the committee, doctor. Your biographical background has not been introduced into the record. I do so now by reference and ask that it be placed at the beginning of my remarks.

Senator BURDICK. According to historical data in 1900, an infant born in America faced a 1 in 10 chance of dying before his first birthday. By 1950, the overall infant mortality rate had fallen by two-thirds. From 1965 to 1982, infant mortality began another sharp decline.

It appears that the rate of decline has slowed significantly. In your opinion, has the administration cut the role in the design of this progress?

Dr. KOLB. Yes. Yes; I believe it has, sir.

Senator BURDICK. The answer is yes. You say the United States ranks 15th in infant mortality among nations having a population of more than 2 million. I understand in the past 20 years, the United States has never ranked higher than 13th on the list of countries with lowest infant mortality rate. Why is our record so poor?

Dr. KOLB. Due to multiple factors, sir, is why our infant mortality is so poor. I think I addressed those briefly in my statement today.

Senator BURDICK. Fine, which I will read.

A recent study by the Institute of American Pediatrics showed that providing adequate prenatal care to women who need to receive it reduces the low birth weight rate by 15 percent. The same study concluded that preventing low birth weight would be cheaper than providing the intensive neonatal care to the babies weighing less than 5 pounds, claiming that Federal investment in prenatal care would net yield a net return of between $12 and $20 million a day.

Would you agree?

Dr. KOLB. That is correct.

Senator BURDICK. I have also heard in terms of preventing low birth weight, prenatal care saves $3 for $1 spent. Is that an accurate statement?

Dr. KOLB. To my knowledge it is, sir.

Senator BURDICK. In the overall need in the context of caring for children, how can this subcommittee provide that sense of direction?

Dr. KOLB. I think to be supportive of the many programs that your subcommittee has jurisdiction over. You have many programs which involve infants, which involve parents, some others and children, be it from the transition to supportive research in NICHD doing major research in the low birth weight infant.

I think the support of this committee for the programs that involve children, not only in care, but also in research, would be the way that we can best serve the needs of our children of our society. They are at risk; they are at major risk.

Senator BURDICK. You forgot one little thing. [Laughter.]

We need some funds to renew those nice things. I agree with you.

Dr. KOLB. Yes.

Senator BURDICK. I agree with you. Thank you.

Senator WEICKER. I will say one thing, time and again, time and again, like Senator Andrews, Senator Burdick has just stood up time and again and supported funding and supported the unpopular, according to the political wisdom of the day, and has been a very valuable ally in all of this.

Thank you very much, Dr. Kolb.

Dr. KOLB. Thank you, sir. Thank you, Senator Andrews.

Senator WEICKER. The next witness is Jacqueline Bellanti, chairperson of the National Coalition on Immune System Disorders.

STATEMENT OF JACQUELINE BELLANTI, CHAIRPERSON, NATIONAL COALITION ON IMMUNE SYSTEM DISORDERS

ACCOMPANIED BY:

WIN TURNER
MARCIA BOYLE
SUSAN GOLICK
MAGGIE PETITO
WON DAVEY
LEN COCH

Ms. BELLANTI. Mr. Chairman, I would like you to wait just a second so that the people accompanying me here today could join me at the table.

Senator WEICKER. Fine, take your time.

Ms. BELLANTI. Thank you, Senator. My name is Jacqueline Bellanti, and I volunteer to chair the National Coalition on Immune System Disorders. This organization was formed in 1983 and is now composed of 12 organizations representing voluntary and health professional groups that are interested in the immune system in health and disease. The people with me today represent individuals with disorders of the immune system, and I would like them to introduce themselves.

Mr. TURNER. I am William Turner, and I am with the Multiple Sclerosis Society, and I represent them on the coalition.

Ms. PETITO. David?

Mr. PETITO. My name is David. I have asthma; sometimes I can't breath right.

Ms. Bellanti. Davey has asthma.

Senator Weicker. Hey, David, how are you?

Mr. Petito. Good.

Ms. Bellanti. He has got his mother with him.

Senator Weicker. Davey, nice to have you here, and your mother, too. We are delighted.

Ms. Golick. I am Susan Golick, and I am a patient with lupus erytematosus, and I represent the Lupus Coalition of America for America.

Ms. Bellanti. Johnny, it is your turn.

Ms. Boyle. This is John Boyle. I am John's mom. John is one of tens of thousands of children with a primary immune deficiency disease. I am the president of the Immune Deficiency Foundation, and Johnny is lucky. But most patients are not so lucky.

Senator Weicker. John, nice to have you here.

Mr. Koch. I am Len Koch. I have had insulin dependent diabetes for over 25 years, and I currently suffer from diabetic retinopathy which is a degenerative condition of the retina.

Senator Weicker. It is a great pleasure to have all of you with us at the committee. I think it is terrific to bring in those persons affected. It makes the testimony all the more meaningful.

Ms. Bellanti. In addition to the people sitting at the table, there are an estimated 65 million Americans with disorders of the immune system. The reason these organizations are joined together is because they are interested in the immune system. They want to speak with one voice on behalf of the immune system and to tell you about the urgency to continue and not to cut, to expand, and not to decrease that funding.

I guess first of all and most importantly, Mr. Chairman, it is important for us to say thank you, because it was this committee that, through its outstanding and strong commitment, has created the immunology initiative, and we would not be this far. That light is going to bother me, so I am going to move along.

I have submitted with our testimony a written statement and along with it the brochure which contains all of the organizations and the mission statement, and I would like the record to show that that has been submitted, because given the time we are allowed, I am not going to be able to go through that.

Perhaps the first important thing for us to tell you today is that we are, as a coalition, representing more than 65 million Americans with disorders of the immune system, and we are members of the ad hoc group for medical research that supports the recommendations for a budget for $6.1 billion at the NIH.

We recently received the immunology report from the National Institutes of Health, and we are impressed by the fact that immunology and its research is occurring at every institute within the NIH.

But to cut the NIH for its moneys is going to devastate, No. 1, a critical mass of well-trained immunologists to provide the skills, the need to provide adequate training, grant support, to encourage immunology research in the neonatal development and in the newborn. The gentleman from the American Academy of Pediatrics has mentioned this, the growth and research career awards to assure the continuation of scientific contributions.

Our pool of investigators is dwindling and there is no one standing in the wings that is going to take up this challenge to continue this research.

And the addition and separate funding for the problem of acquired immune deficiency syndrome [AIDS], even though it is an immunology problem, many of our people are saying that a lot of the moneys are moving toward AIDS and a lot of the resources are going to find the answers to that problem, and that leaves these individuals and 65 million others saying, yes, that research is important, but they are also important.

Then the support of research centers to full funding to assure that clinical research and the clinical trials that you spoke about. We need upgrading and renovation of the primate centers because they are outmoded and inefficient and supported for intramural grants. Immunology is probably our best investment in the future.

As a matter of fact, you and I sat opposite this table last year and you were speaking to a gentleman who was with infectious disease. I think it was Dr. Wolff saying in the long term, where are we going to get our best benefits? I think for 65 million Americans, standing there waiting for research to improve their care, immunology, and the research on immunology initiative is most important, and I thank you very much on behalf of all of us for the opportunity to speak.

PREPARED STATEMENT

Senator **WEICKER**. Thank you for your testimony. We will place your statement in its entirety in the record at this point.

[The statement follows:]

STATEMENT OF JACQUELINE BELLANTI

My name is Jacqueline Bellanti and I volunteer to Chair the National Coalition on Immune System Disorders (NCISD). This organization was formed in 1983 and is now composed of 12 organizations representing voluntary and professional health groups interested in the immune system in health and disease. The people with me today represent individuals with disorders of the immune system and I would like them to introduce themselves (attachment #1). In addition to these people here, there are an estimated 65 million Americans, almost one in four of the population of the United States, with disorders and diseases of the immune system. These people--65 million strong, call upon this Committee and its members not to let them be forgotten. We are here today to speak with one voice on behalf of research on the immune system and the urgency to continue-not cut-, to expand-not decrease-the funding for that research.

First, and most important, we would like to express our sincere appreciation to you, Mr. Chairman and the other members of this Committee for your outstanding support and strong commitment to research endeavors in the field of immunology. It has been because of your continued efforts that the immunology initiative has flourished and because of this we are closer to learning more about the immune system and its important functions. Thank you for your encouragement in the past, but we ask you not to abandon us now.

I would like to draw your attention to the brochure attached to this testimony as it contains the names of the Board of the National Coalition on Immune System Disorders: The AIDS Action Council; the American Academy of Otolaryngology-Head and Neck Surgery; the American Lung Association; the Arthritis Foundation; the Asthma & Allergy Foundation of America; the Immune Deficiency Foundation; the Joint Council of Allergy & Immunology; the Lupus Foundation of America; the National Foundation for Ileitis & Colitis; the National Multiple Sclerosis Society and the Terri Gotthelf Lupus Research Institute

Broadly speaking, our statement of purpose is our profound and continued interest in the immune system-in health and disease- and the need for reseach on that system as well as the translation of that research to the benefit of the American people. With the increased knowledge of the immune system and the explosion of information on that system, there is heightened expectation of the application that research on the immune system may lead to. Recent research efforts in basic and clinical immunology have put us on the threshold of discovering new insights in the mechanisms of this complex system which can lead not only to improved methods of diagnosis and treatment but conceivably curing some of these disorders of the immune system. Will all this research disappear? If this research diminishes, so does the hopes of millions of people who depend on this research to sustain them not only in their daily living but in research lies the hope for cures and improved treatment. There are those who wish to tell this to the American people-"there are more important issues than research for your disease"

Consider the impact of the challenge facing researchers today. It is estimated that approximately one in four Americans has a disorder or disease of the immune system:

- 73 million Americans have chronic respiratory problems;
- 40 million Americans have asthma or allergic diseases;
- 38 million Americans have arthritis (250,000 are children);
- one-half million Americans have systemic lupus erythematosus (9:1 are women).
- 11 million Americans have diabetes;
- one-quarter million Americans have multiple sclerosis;
- 19,000 Americans have AIDS and over 1½ million are infected with the virus.
- 250,000 million Americans have an immune deficiency disorder;
- 20 million Americans have hearing impairment;
- 2 million Americans have ileitis and colitis;

The range of diseases is great: allergies to arthritis to AIDS; the quality of life for those with immunologic disorders is equally diminished. There are many other serious diseases and disorders, including cancer, with are suspected to be related to immune system dysfunction.

The NCISD is appealing today with one voice to support the immunology initiative begun in 1981 by this Committee and to fund it to the degree where research efforts may afford a breakthrough for the cure for many disorders of the immune system. The statements that follow reflect the importance of research in the field of immunology and the impact that cutbacks have had and what the future holds:

American Academy of Otolaryngology-Head and Neck Surgery: More than 50,000 Americans will develop cancer of the head and neck this year. 15,000 of them will die. Immunological techniques and interventions are our most exciting avenues to earlier diagnosis and more effective treatment for these patients. Autoimmune diseases often affect hearing and balance. A significant number of young people who see an otolargngologist about recurrent dizziness are experiencing this vertigo as the first symptom of multiple sclerosis. We know too little about the relationship of the immune system to normal hearing and balance. We are concerned, too, with better treatment of infections and allergy affecting the ear, nose and throat and with improving the outcome of any surgery involving the head and neck. We are already taking advantage of new knowledge about the immune system. However, the continuing uncertainty over actual and future levels of Federal funding for health-related research is serious comprimising our ability to evaluate promising new strategies of care for our patients. Efforts to restrain Federal spending cannot be allowed to strangle clinical application of what we have already learned about the immune system, Mr. Chairman. Our patients need increased NIH support of immunological research, training and clinical research, not less. Actions taken in Fiscal Year 1986 and contemplated for Fiscal Year, 1987 will have long range consequences. Fewer talented young men and women can be attracted into clinical research careers, when they see their mentors losing grants and constantly scrambling to keep important projects going despite cuts in funding. Even the most creative clinical investigators must now divert so much time to fundraising that valuable studies simply go undone or are delayed indefinitely. Some experienced investigators have abandoned clinical research altogether. If this continues, damage to the remarkably productive relationship between the Federal Government's National Institutes of Health and the biomedical research community will take years to repair and a whole generation of patients will endure needless death and disability.

American Lung Association: The lungs remain the single most common target organ for infection in immunocomprised patients, which include patients undergoing cancer chemotherapy, recipients of an organ transplant, or those who are generally debilitated. Such patients are subject to "opportunistic" infections by a wide variety of common microorganisms that rarely cause disease in immunologically normal persons. More recently, these infections have been seen in patients with AIDS. Through better definition of various naturally occuring defenses against infection, such as interferon, and with the use of recombinant DNA technology to supply these products in large amounts, effective treatment and prevention could take a giant step forward.

National Multiple Sclerosis Society: Multiple sclerosis is now thought to be a neurologic disease of immunological origin. Tremendous strides in understanding the immune system are being made by the NIH. Cut backs in biomedical research would be cruel, shortsighted and in the long run, very costly by delaying cures for multiple sclerosis and other immune system disorders that costs billions in health care.

American Diabetes Association: Research regarding the immune system is relevant to the disease diabetes mellitus. Diabetes mellitus is a chronic disorder characterized by abnormalities in the metabolism of carbohydrate, protein and fat. It is thought that insulin-dependent diabetes is an autoimmune disease, in that the body unexpectedly begins to make antibodies against its own pancreas, thereby destroying the insulin secreting function of this organ. The event that triggers the autoimmune reaction, as well as a thorough understanding of the autoimmune process itself are unknown. More research in this area would undoubtedly lead to ways to prevent and possibly cure, diabetes

Asthma & Allergy Foundation of America: We are dedicated to serving the 40 million Americans with asthma and allergic diseases by supporting scientific research to find the means to prevent and ultimately cure these disorders. Research on the immune system and its functioning is vital to the cause and cure for asthma and allergic diseases. We are concerned that cut-backs will diminish the number of research centers devoted to research on asthma and allergic diseases and that the pool of investigators will be so diminished that cures through research will be impossible.

AIDS Action Council: Recognizing that AIDS is one of the most serious threats to the body's immune system to appear in this century, the AIDS Action Council places top priority on securing funds to support immunological research and treatment. Scientific advances in AIDS-related immunological research will significantly enhance the fight against all immune system disorders. Of particular importance are plans to develop drugs that block the antigenic assaults on the body's immune system as well as drugs that strengthen the immune system's ability to fight off infection.

Terri Gotthelf Lupus Research Institute: Lupus is not a rare disease. One out of 700 women suffers from lupus, the majority in their twenties and thirties. Despite the prevalence and pervasiveness of this disease, we still do not know the factors causing it, nor how to prevent or cure it. Through the Terri Gotthelf Lupus Research Institute and working with the governmental and private sectors, we hope to move forward against this deadly disease by improving the effectiveness of our research programs on immune diseases.

Joint Council of Allergy and Immunology; The JCAI, comprised of the American Academy of Allergy and Immunology, the American College of Allergists, and the American Association for Clinical Immunology and Allergy feels that progressive research on the immune system is critical in the eradication of asthma and allergic diseases which are among the nation's most common, costly and misunderstood health problems. Cutbacks in research can only prove to be far more costly in the long run for the government in treatment for the millions of Americans afflicted with these disorders.

Arthritis Foundation: This Foundation is the only national voluntary health agency working to find the answers for all forms of arthritis as well as supporting public and professional education programs. In certain types of arthritis, the immune system malfunctions so that healthy body cells are attached by antibodies, thus research on the immune system is of great importance to people with arthritis, arthritis researchers and the Arthritis Foundation.

National Foundation for Ileitis and Colitis (NFIC): The NFIC is devoted to raising funds to discover the elusive cause and cure for Crohn's disease and ulcerative colitis. It is estimated that as many as 2 million Americans have these disorders and they are primarily diseases of the young. The body's immune system appears to play a significant role in both the susceptibility to and the course of inflammatory bowel disease. The cure for ileitis and colitis lies within the mysteries of the immune system and further research is needed to find the answers and provide hope to the more than 2 million Americans of which there are 200,000 children under the age of 16 years.

The Immune Deficiency Foundation (IFD): The IDF was founded in 1981 to promote scientific research into the cause, prevention, treatment and cure of the primary immune deficiency diseases. The Foundation also supports clinical training and coordinates and disseminates information concerning research and treatment of these

diseases. Of great interest is the need to expand resrarch in the developing immune system in infants and children because the susceptibility of the developing infant to infection is related to the immature immune system and research is vital to determine both the cellular and humoral mechanisms of the defense system to answer why they are more vulnerable.

Lupus Foundation of America (LFA): Systemic lupus erythematosus,an autoimmune disease of unknown cause, afflicts 500,000 people in the U.S., with 16,000 new victims each year. The LFA and its 95 chapters across the country seek to promote public, professional and patient awareness and education and encourage, monitor and directly sponsor research on the causes, treatment and cure of lupus. Annually, the LFA awards several research fellowships and grants. However, this debilitating and sometimes fatal disease, which disproportionately strikes women and minorities, requires continued and strengthened public research support if the cause of, and cure for lupus are to be soon found.

Congressional Initiatives

The NCISD is a member of the Ad Hoc Group for Medical Research and supports the recommendations of a budget of $6.1 billion for the NIH. This is a modest program growth of about $~~86 million or~~ 1.4% over the current services budget. This increase provides funds sufficient to support research activities at levels provided by the FY 86 congressional appropriations with only a modest increase for a variety of important programs to conduct basic and clinical research, train qualified promising investigators and translate that research and technology to the benefit of the public. This Committee has demonstrated its support by creating and nuturing the immunology initiative of 1981 and to further this research initiative, the NCISD requests report language to assure the following:

- a critical mass of well-trained **immunologists** to provide necessary skills and expertise; need to provide adequate training grant support;
- encourage immunology research on the maturation of the immune system during development, fetal and neonatal host defenses against infection and disease;
- growth in research career awards to develop vigorous research groups at medical schools specializing in immunologic diseases;
- encouragement of clinical trials to assure the continuation of scientific outreach and technology transfer for the benefit of the public;
- additional and separate funding for the cause, treatment and cure of AIDS--the major health crisis of this century;
- support of research centers to full funding to assure the clinical research efforts on the cause, prevention and treatment of asthma, immune deficiencies and autoimmune disease. Fully support the core outreach of centers for the education and technology transfer components;
- develop methods to treat colitis, ileitis and other intestinal disorders, many of whom have immunologic origin;
- needed upgrading and renovation of primate centers and outmoded and inefficient research laboratories--both intramurally and in medical school settings;
- support for intramural and R&D contracts to maintain all on-going efforts in respiratory, immunologic, rheumatologic and autoimmune diseases;

Research in immunology is our best investment in the future; to support it we need the scientists, clinicians and the funding to provide hope for the more than 65 million Americans with immunologic disorders. Thank you Mr.Chairman, Committee members for the opportunity to present before you today.

Senator WEICKER. Would any of you like to speak individually for a few minutes? If there is anybody here that cares to speak up in this group, please do this.

Ms. BELLANTI. Marcia?

Ms. BOYLE. I mentioned that John is one of tens of thousands of immune deficient children. I will also say, even though he is a little embarrassed, he is an A student in second grade, he plays many sports, and he hasn't been hospitalized in 5 years. The first couple of years were not so nice, as they are right now. His bubble, and the bubble is the concept, I think, with the primarily immune deficiency diseases, really, are the drugs and treatment that have been developed through the years by the National Institutes of Health.

There are children like John across the country that hope that you will support their future. Most aren't as lucky as John, and the fortunate ones, even fortunate ones have many question marks in their futures. So we, for all of immunology, and particularly as I am talking for immune deficiency diseases, hope that you will maintain the funding, increase the funding and not let the momentum fall.

Senator WEICKER. Thank you very much.

Ms. BOYLE. Thank you very much.

Ms. GOLICK. I would first of all like to congratulate you for your outstanding support and continued commitment over the past year for research into the immune system disorders. Lupus is a disease striking between 500,000 and 1 million Americans, and it discriminates, it is about 9 to 1 females. They are women basically in their childbearing years, in their prime of life, and we desperately need your help to continue support and to be sure that in this very difficult time in the budget making process that there can be no higher priority in this society than human life, and we look to you for that support.

Thank you.

Senator WEICKER. OK.

Ms. BELLANTI. Do you want to tell how many times Davey has been in the hospital?

Ms. PETTO. My son has been in the hospital dozens of times, and dozens more for nonextended visits. I can also speak for just the millions of people with children that have pediatric asthma, allergies and immune problems, that we appreciate your support and are concerned for these issues.

It is heartbreaking when you see your little one in trouble, but it is rewarding to know there is movement toward research to help find a cure for these situations. Thank you.

Ms. BELLANTI. Thank you, Mr. Chairman.

Senator WEICKER. Thank you all. I thank you all very much for making the effort, taking the time to be here with us. I can assure you that we will do everything that we possibly can on the matters up before the Senate right now to increase funding. Again, I have to say to all of you, I think the thing that bothers me is what bothers you: That even the increases which Senator Burdick and I and others can attach to the bill are a pitance compared to what this Nation really is capable of.

I will tell you, what makes me mad as hell is we can spend billions and billions on the speculation, on the speculation as to what might happen if so-and-so goes to war with the United States. I think it is great to be compared, but that is speculation. What we have before us here is fact, and we are unwilling to deal with that, and that is a very frustrating situation for me, as I am sure it is for all of you.

Thank you very much.

Ms. BELLANTI. It is one of the reasons that these groups came together, because that in separate numbers, they are their own entity. When they come together, it is a tremendous number of people suffering from the same thing.

Senator WEICKER. It is.

Ms. BELLANTI. Thank you very much, Mr. Chairman. I appreciate your time.

STATEMENT OF SHELDON M. WOLFF, M.D., INFECTIOUS DISEASES SOCIETY OF AMERICA, CHAIRMAN, DEPARTMENT OF MEDICINE, TUFTS UNIVERSITY

Senator WEICKER. Dr. Sheldon Wolff of the Infectious Disease Society of America. Dr. Wolff is the chairman from the Department of Medicine of Tufts University.

Dr. WOLFF. Senator Weicker, thank you very much. I would like to take this opportunity to express the Infectious Diseases Society of America thanks to you and your committee on the National Institute of Allergy and Infectious Diseases.

As you well know, the mission of that Institute extends to the prevention and control of infectious and immunologic diseases. These are the areas of science and medicine that are of overwhelming concern to the American public. Considering that scientists continue to discover that diseases once believed to be largely noncommunicable are, in fact, spread by vires, this public concern is well-founded. For example, over 80 percent of the world's 250,000 cases of liver cancer are directly attributable to hepatitis-B virus.

The AIDS virus continues to menace the public health. In fact, the rate of Americans being struck by this devastating disease is continuing at an alarming rate. There are now over 189,000 recorded cases of AIDS in the United States. While this is substantially below the 350 per 1 million incidence rate found in Zaire, it is clear that we must act quickly to prevent further spread of this fatal disease. Since medical costs alone for AIDS patients range from $45,000 to $140,000, the investment of dollars and the research required to find ways to prevent and combat this dreaded disease will yield enormous real dollar returns and, more importantly, assuage the fears of millions of people that they, too, will be victimized by this epidemic.

The National Institute on Allergies and Infectious Diseases [NIAID], however, cannot dedicate itself exclusively to the pursuit of cures and treatments for the myriad infectious diseases that plague us at home and abroad if its attention and efforts are constantly being diverted by myopic administrative and congressional actions such as:

The rigid funding apportionment policies instituted by the Office of Management and Budget [OMB]; the precipitous across-the-board funding reductions occasioned by the Gramm-Rudman Act; and the Public Health Service's management decision to consolidate all AIDS funding in the Office of the Assistant Secretary of Health.

I would like to discuss briefly each of these actions.

Biomedical research simply cannot flourish in the highly bureaucratic environment that is being created by the OMB. Specifically, the OMB, which is, as we all know appears to be embarking on a vendetta against the NIH, has instituted a rigid funding apportionment process that leaves NIH institute directors with virtually no flexibility to make crucial operational management decisions that can and do enhance the quality and timeliness of the research that is funded.

For example, institute directors are virtually precluded by the OMB apportionment policies by moving even a small amount of funds from R–01 research grants to promising clinical trails, irrespective of the need or merits of reallocation of funds.

In other words, it has almost become the case that it is the OMB and not the NIH that dictates the course of the Federal biomedical research effort. It hardly needs to be mentioned that this is a job for which the OMB staff lacks the requisite scientific expertise or outlook.

The 4.3-percent reduction in biomedical research funding occasioned by the March 1 Presidential sequestration order, inspired by the Gramm-Rudman Act, adversely impacted upon all of the research efforts supported by the NIAID. Specifically, as regards the NIAID, funding for nearly all of NIAID's research grants had to be cut indiscriminantly by an average of 10 percent and the number of individual awards for research trainees reduced from 85 to 69.

These Gramm-Rudman across-the-board funding cuts are an anathema to a vital and productive research enterprise. Worse still, however, are the optimistic Congressional Budget Office predictions that the next round of sequestration cuts scheduled to go into effect September 1 will reduce the NIAID's funding by at least an additional 8.4 percent.

This percentage cut will reduce the NIAID's budget by nearly 13 percent below the 1986 appropriation level within a span of 7 months.

The administration has recommended that all AIDS funding be consolidated in the Office of the Assistant Secretary of Health in order to, and these are their words, "highlight, plan and coordinate the total level of resources being devoted to this top public health priority."

While this appear fine on paper, in effect, it will remove 17 percent of NIAID's total budget under the direct control of the assistant Secretary.

Further, this will increase layers of bureaucratic paperwork and unnecessarily hamper our research in AIDS. The rest of my presentation has been presented for the record, Mr. Chairman, but let me once again just say that we greatly appreciate all of your efforts on our behalf in the past and hope that it will continue in the future.

PREPARED STATEMENT

Senator WEICKER. I think the principal points you have made are right on the mark in all respects. I thank you very much.

Dr. WOLFF. Thank you.

[The statement follows:]

STATEMENT OF SHELDON M. WOLFF

Mr. Chairman, and members of the Committee, my name is Sheldon M. Wolff. I have for the last nine years been Chairman of the Department of Medicine at Tufts University School of Medicine, and Physician-in-Chief of the New England Medical Center. From 1960 through 1977, I was privileged to work at the National Institutes of Health. In 1968, I became Clinical Director of the National Institute of Allergy and Infectious Diseases, and Chief of its Laboratory of Clinical Investigation. I presently hold an NIH research grant, and the department for which I am responsible conducts research under NIH grants and contracts that total several millions of dollars. In addition, I am a member of the National Advisory Council on Allergy and Infectious Diseases.

My testimony today is presented on behalf of the Infectious Diseases Society of America, an organization of physicians and scientists dedicated to the sharing of knowledge and the fostering of research in the area of infectious diseases. I am at present the Chairman of its Public Policy Committee, and I am past-President of the Society. We represent the overwhelming majority of infectious diseases specialists in this country and, in particular, those individuals involved in clinical and basic research in infectious diseases.

Mr. Chairman, I would like to take this opportunity to express the IDSA's appreciation to you for your support for the National Institute of Allergy and Infectious Diseases (NIAID). As you well know, the NIAID's mission extends to the prevention and control of infectious and immunologic diseases. These are the areas of science and medicine that are of overwhelming concern to the American public. Considering that scientists continue to discover that diseases once believed to be largely noncommunicable are in fact spread by vires, this public concern is well-founded. For example, even some forms of cancer have been identified as infectious diseases communicable through blood, childbirth or mother's milk. Presently, over 80 percent of the world's 250,000 cases of liver cancer are directly attributable to the hepatitis-B virus.

The AIDS virus continues to menace public health. In fact, the rate of Americans being struck by this devastating disease is now **700** times as high as it was in 1980. It is estimated that the incidence rate of AIDS in the United States is 35 per million. While this is substantially below the 350 per million incidence rate NIAID researchers found in Zaire, it is clear that we must act quickly to prevent further spread of this fatal disease before we are faced with a ten fold increase in our incidence rate. Since medical costs alone for AIDS patients range from $45,000 to $140,000, the investment of dollars in the research it requires to find ways to prevent and combat this dreaded disease will yield enormous real dollar returns and, more importantly, assuage the fears of millions of people that they too will be victimized by the AIDS epidemic.

The NIAID, however, cannot dedicate itself exclusively to the pursuit of cures and treatments for the myriad infectious diseases that plague us at home and abroad, if its attention and efforts are constantly being diverted by myopic administrative and congressional actions, such as:

- The rigid funding apportionment polices instituted by the Office of Management and Budget (OMB);
- The precipitous across-the-board funding reductions occasioned by the Gramm-Rudman Act; and
- The Public Health Service's "management" decision to consolidate all AIDS funding in the Office of the Assistant Secretary for Health (OASH).

I would likely to discuss briefly each one of these actions and how it has or will impact upon the NIAID's biomedical research effort.

Biomedical research simply cannot flourish in the highly bureaucratic environment that is being created by the OMB. Specifically, the OMB - - which as you well know appears to have embarked on a vendetta against the NIH - - has instituted a rigid funding apportionment policy that leaves NIH Institute Directors with virtually no flexibility to make crucial operational management decisions that can and do enhance the quality and timeliness of the research that is funded. For example, Institute Directors are virtually precluded by the OMB apportionment policies from moving even a small amount of funds from R01 research grants to promising clinical trials, irrespective of the need or merit of such a temporary reallocation of funds. In other words, it has almost become the case that it is the OMB, and not the NIH that dictates the course of the Federal biomedical research effort -- and it hardly requires mention that this is a job for which the OMB staff lacks the requisite scientific expertise or outlook.

The 4.3 percent reduction in biomedical research funding occasioned by the March 1 presidential sequestration order -- inspired by the Gramm-Rudman Act -- adversely impacted upon all the research efforts supported by the NIAID. Specifically, under the sequestration order, funding for each and every NIAID research grant was cut indiscriminatly by 4.3 percent, and the number of individual awards for research trainees reduced from 85 to 69. These Gramm-Rudman across-the-board funding cuts are anathema to a vital and productive research enterprise. Worse still, however, are the "optimistic" Congressional Budget Office (CBO) predictions that the next round of sequestration cuts, scheduled to go into effect September 1, will reduce the NIAID's funding by at least an additional 8.5 percent. This percentage cut would reduce the NIAID's budget by nearly 13 percent below the FY 1986 appropriation level within a span of seven months, virtually emasculating the Institutes' research efforts and all but bringing to a halt our progress toward irradicating and controlling the spread of infectious diseases. It is hard for me to believe that the American public, who overwhelmingly supports this nation's biomedical research effort, is in favor of cuts of this magnitude or description.

The administration has recommended that all AIDS funding be consolidated in the Office of the Assistant Secretary for Health (OASH) in order to "highlight, plan and coordinate the total level of resources being devoted to this top public health priority" 1/ While this centralization of funds and planning authority may sound good on paper, it is not in the best interest of AIDS research. First, the proposal will strip the NIAID of over $35 million in AIDS new initiative funds and $26 million in base support. In effect, 17 percent of the NIAID's total budget will be under the direct control of OASH. Second, consolidation of AIDS funds will greatly hamper the ability of the NIAID to plan effectively the course and direction of its AIDS research effort by adding unnecessary layers of bureaucracy to the decision making process. Admitedly, coordination of the federal effort against AIDS is desirable. However, centralizing absolutely the control of funding and research strategy under the OASH will effectively thwart the NIAID's long range planning efforts and prevent the Institute from responding quickly to important AIDS research opportunities; and thus, it is not in the best interest of a dynamic and effective research effort.

As if the constraints on research imposed by the OMB, the AIDS funding consolidation plan and the Gramm-Rudman cuts weren't sufficient detriments to the conduct of biomedical research,

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1/ U.S. Department of Health and Human Services "The Fiscal Year 1987 Budget" (HHS Handout).

the budget for the NIAID for FY 1987 requested by the administration recommends a seven percent decrease below last year's appropriation and would precipitate a loss of 87 new and competing research grants. In the judgment of professional scientists, the NIAID could use productively a funding increase of nearly $170 million. Thus, the cut of $26 million, or 7 percent, below the FY 1986 appropriations level that the administration has requested is simply unthinkable because of the irreparably damaging effect it would have on the Institute's research programs. The NIAID must receive a funding increase of at least eleven percent above its FY 1986 appropriation if it is to maintain ongoing research efforts and ensure that real scientific progress is made toward preventing and controlling numerous infectious diseases.

Mr. Chairman, on behalf of the infectious diseases research community, thank you again for your support for the NIAID's work, and for biomedical research generally. We sincerely appreciate your leadership. I will be happy to answer any questions you or the other members of the committee may have.

STATEMENT OF THEODORE W. VAN ZELST, CHRONIC EPSTEIN-BARR VIRUS INFECTION

Senator WEICKER. The next witness is Theodore W. Van Zelst, chronic Epstein-Barr virus infection [CEBV].

Mr. VAN ZELST. Mr. Chairman, I am here today representing myself as an individual and also as president of Minann, Inc., a charitable foundation which has been actively involved in chronic Epstein-Barr virus infection matters.

Two years ago, I appeared before this subcommittee to present testimony on this disease 2 years ago and appear today to give an update. What are the typical symptoms? A recent survey indicates that people who have been ill with this disease 2 years or more 80 percent of time reported debilitating fatigue, muscle aches, sore throat, headaches, dizziness, and depression. Seventy-one percent of the patients are between the ages of 22 and 44, and 75 percent of them are female.

The disease is sometimes called chronic mononucleosis. The question that was asked the last time I appeared was: What is the incidence of this disease. I think the activity in the last 18 months will give some indication. We have received 7,000 requests for CEBV information bulletins. We have received 1,700 letters detailing how the illness has affected the writers and devastated their lives.

We have had 1,200 responses to a medical survey, with 702 of those reporting a positive indication of having this disease. The national support group was organized last fall and has already received 2,500 inquiries regarding the disease in the first 3 months of this year.

Over 100 self-support groups have been organized during the last year. More than 30 media articles have appeared on this disease, and there have been numerous radio and television presentations, including one on a major station on the "Ten O'clock News" in Chicago last night. There also have been numerous technical articles that are starting to appear in medical journals.

I think relying on all of this represents pretty much patient effort. I think we need other ways, finding other ways to seek out the information of the incidents. The plight of the people involved can sometimes be told by some of the excerpts from letters that we have received. I will just repeat a few of them.

From Pennsylvania:

> Please send my daughter information. She just buried her husband with symptoms relative to what I read about this disease. Now she has the similar symptoms. After countless doctors and testing, she has no answers. She is 31.

Another patient wrote, "CEBV has wrecked my career, my marriage, and my physical well-being."

From the patient in the East:

> I have chronic Epstein-Barr virus, and I can't find a doctor who knows it exists. I don't know how to get Social Security disability when the doctors know little about this illness. My husband divorced me. I have no money for heat. Without help, financial and medical, I cannot survive.

I have asked some of the researchers on this disease to comment on their studies and some of their future objectives. Dr. James Niederman at Yale University says:

> The objective of my ongoing research on chronic EBV infections is to characterize more precisely the syndrome of chronic infectious mononucleosis and to identify specific serologic markers for differentiations of latent asymptomatic CBV infection from chronic active symptomatic infection. We anticipate that the syndrome of chronic mononucleosis will likely include a heterogenous group of disorders.

Dr. James Jones, one of the senior researchers from the National Jewish Medical Center in Denver evaluates and defines the CEBV syndrome as a virus different in this syndrome as different from the infection which apparently causes mononucleosis.

And Dr. Komaroff from the medical school says that with the cooperation of the National Institutes of Health in North Carolina and Massachusetts, "We are pursuing the research for either a new strain of EBV or another virus which reactivates CBV."

There are new concerns about this disease, as there are recent reports of all epidemics occurring. At Christmas time in Incline Village, CA, there were 149 cases recorded. At Yerington, NV, in November, nearby, 40 cases. In San Francisco recently, another 40 cases.

Dr. Komaroff and his colleagues are researching this. We ask this subcommittee to recommend that the National Institute of Allergies and Infectious Diseases conduct or sponsor more research on the chronic form of the Epstein-Barr virus infection in search of better techniques for diagnosis, treatment, and, hopefully, an eventual cure, and that a protocol be established to the NIH or the Centers for Disease Control for reporting the incidence of the chronic forms of Epstein-Barr virus by physicians.

This reporting should be set up as a clearinghouse of medical information to assist physicians, researchers, and patients.

Thank you for the opportunity to present this testimony.

PREPARED STATEMENT

Senator WEICKER. Thank you very much, Mr. Van Zelst, I appreciate it.

[The statement follows:]

STATEMENT OF THEODORE W. VAN ZELST

Mr. Chairman, my name is Theodore W. Van Zelst. I am here today as a private individual and also as president of Minann, Inc., a charitable foundation which for the past three years has been actively involved on matters related to a relatively unknown disease, Chronic Epstein-Barr Virus Infection (CEBV).

Two years ago I appeared before this Subcommittee to tell about CEBV and requested that more research on this disease be conducted under the direction of the Institute of Allergy & Infectious Diseases of the National Institutes of Health. Because of the interest of this Subcommittee, we believe that there has been more CEBV research by NIH, but much more needs to be done.

Epstein-Barr virus (EBV) is a ubiquitous virus that causes infectious mononucleosis in adults and often results in subclinical infection in children. During the past two years, those concerned with this debilitating illness have not just waited for governmental action. Much as been done by individuals and group efforts throughout the country.

Two technical articles and an editorial about Chronic Epstein-Barr Virus Infection appeared in the Annals of Internal Medicine in January 1985. Nationwide attention was drawn to CEBV when there was heavy coverage about CEBV in news magazines, the daily press, radio and TV. More than 30 articles on the subject have since appeared and there have been numerous features on radio and TV. Mention in the media is not enough because so many people identify the CEBV symptoms as an illness that has plagued them and they search for more information.

An article in the New York Times and subsequent syndication of the story generated over 7000 individual requests to Minann for information about CEBV. Minann took on some of the task of distribution of information about CEBV since we could not find a medical facility willing to accept this responsibility. Minann printed a CEBV Information Bulletin covering facts and often asked questions about the illness. This Bulletin is now in its 4th printing and about 8000 copies have been distributed to those who have learned about CEBV through the media.

Minann has received over 1300 letters from patients and those who suspect they might have CEBV. A support group in Tucson received hundreds of inquiries. A national support group in Portland received over 2500 requests in the first three months of 1986. Many of these writers are articulate people who describe their symptoms, the difficulty in diagnosis, their lack of hope, and their concern about the future.

The published information on CEBV has helped many people and assisted in the development of self-help support groups around the country. A National CEBV Syndrome Assoc. has been formed in Portland, Oregon and an affiliate, CEBRA of New York is now organized to assist in the eastern United States. Support activity continues to expand rapidly as new patients learn of these organizations. There are now over 100 CEBV volunteer support groups in the USA.

The availability of support groups, technical information, reports which have been published, all have given hope to some patients with this illness, even though at this time there is no treatment or cure for CEBV.

At my first appearance before this Subcommittee, I reported that we had conducted a survey among doctors and that we had a response from 18 out of 20 contacted. Now, we are in contact with more than 700 doctors as a result of their inquiries for information about this disease. There have also been some medical studies with support from people interested in CEBV. Many doctors have donated time and additional private support has come in funding for laboratory tests, computer time, and volunteer assistance. People concerned about CEBV have not relied on government alone. But, for the major research breakthroughs, much more concentrated research is needed. There are a number of recent research developments that warrant continuation of research by those who have been concentrating their work on this disease.

New concerns about this disease have developed. In addition to individual cases which have been reported previously, there may be small epidemics of CEBV occurring. An outbreak of a reported 140 cases of CEBV in the Incline Village, California area in December 1985 is under study. There was a similar outbreak in a rural community, Yerington, Nevada. There was a recent report of a number of cases at a university in Washington, and another of workers in an office building in the New England area. Anthony L. Komaroff, M.D., Chief of General Medicine, Brigham & Women's Hospital and Harvard Medical School is conducting a study on these outbreaks. Data collection has been completed and is now being analyzed. Dr. Komaroff observed that since the California-Nevada outbreaks occurred in epidemic form, it is possible that it is different from the CEBV illness that has been seen in endemic settings, despite many similarities of symptoms and blood test results. This reinforces the need for more research directed to diagnostic methods for CEBV. Doctors have recently become aware of a fairly large number of patients in San Franciso who may be afflicted with this illness. A group of about 40 will be included in the studies.

At my last appearance before this Subcommittee, a question was asked regarding the incidence of CEBV. I believe some of the facts given above, the thousands of requests for information, the 1300 letters to Minann, indicate that the extent of Chronic Epstein-Barr Virus infection is more widespread than had been anticipated.

During the past year, there has been a push for more research on AIDS, a disease of national concern. We believe there should also be great concern about CEBV -- about which relatively little is now known, but which apparently afflicts many throughout the country. The question as to how CEBV is transmitted is yet unanswered.

The Epstein-Barr virus is the virus which causes infectious mononucleosis. Usually the virus goes into a latent phase and remains inactive. For most people mononucleosis lasts no longer than about 3 months. For reasons, not yet identified, some people have the Epstein-Barr virus reactivated or never have it go into the latent phase after initial infection. Many victims have spent thousands of dollars going from doctor to doctor searching for diagnosis.

Even though technical articles on CEBV have been published in medical journals, the search for a diagnosis by many afflicted with this illness is usually in vain.

Doreen Clark, who operates a New Jersey market survey company, prepared a medical survey on CEBV with the assistance of some physician/researchers. With the aid of Minann, this survey was sent to over 2200 people who have some identification with the illness. Over 1200 persons sent in detailed replies, a phenomenal return rate. Data was tabulated from 702 patients who have been diagnosed with CEBV through the titers blood test, an indicator test which may assist in the diagnosis of Chronic Epstein-Barr virus infection. This survey information will be helpful to researchers, and others who are concerned with the incidence and symptoms of those afflicted with CEBV.

Survey data from the Doreen Clark Survey revealed:

In patients who have been ill 2 years or more, 80% reported typical symptoms: extreme debilitating fatigue/exhaustion; muscle aches; sore throat; headaches; difficulty in concentrating; dizziness; depression and irritability. Extreme fatigue was reported to be constant and unrelieved by 64% of the patients.

71% of the patients were in the age group 24 to 44 years old and 75% were female. 75% have attended or graduated from college.

46% reported that they had been ill with CEBV from 2 to 5 years; 24% from 5 to 10 years; and 30% over 10 years. 22% of the patients said other members of their family also have CEBV.

33% reported that they had been denied Social Security disability benefits. Many others indicated that they had been discouraged from filing because they were told the application would be rejected 'because CEBV is not a recognized disease for disability.'

In reviewing the survey, CEBV research physician, Anthony L, Komaroff, M.D., Harvard Medical School, commented that the number of patients over the age of 45 was substantial. Also, the number of patients who had many of the symptoms which they described as 'severe' was quite great. He said that it was encouraging that a large percentage (90%) of the patients said that they would be willing to participate in research.

Dr. Komaroff suggested that it would be important to assess the responses of the 702 survey patients who have at least one positive titers blood test by surveying these patients and their doctors regarding the actual results of the EBV serological panel and the laboratory which performed the testing. This would be an extremely valuable way of determining how this diagnosis currently is being made by doctors, how solidly the diagnosis seems to be based, and would identify those laboratories which are most involved in performing such testing.

The plight of people afflicted with Chronic Epstein-Barr Virus Infection (CEBV) can be be told by excerpts from some of the 1300 letters we have received during the past year. These are not isolated examples; they are typical. When you have been involved with the requests of thousands of people desperately searching for information, you learn about their pain and also how the hope for new research on CEBV will ease some of the emotional pain.

A Pennsylvania woman wrote: ...Please send my daughter the information on CEBV. She just buried her husband...with symptoms relative to what I read about CEBV in the health bulletin. Now, she has the same symptoms. After countless doctors and testing she has no answer. She's 31...

Another patient wrote: ..CEBV has wrecked my career, my marriage and physical well being...

Another writer commented: ..I am 59 years of age and quite sure I have had this illness approximately 30 years. I too have seen many physicians to no avail. I cannot laugh. I cannot cry. I cannot live, nor can I die. My life is such a waste -- I'm very glad for any help...

From New York: I have difficulty in completing a week's work. I don't have the will power to start moving some days. Please send me any information... as well as what to do with respect to moral support. Very often I wish to die rather than keep going on in this condition...

New York: I have recently been diagnosed with CEBV...after years of suffering from unnamed and disabling symptoms. Although I feel relieved to know what is wrong, I have very little information about this disease and am trying to educate myself...

A letter just received from a woman in the East: ...I am in desperate need of help. I have chronic Epstein-Barr virus and I can't find any doctor who knows it exists. I don't know how to get Social Security disability when the doctors know little about this illness. I am too sick to even cook for myself. My husband divorced me and I have had no money for heat for the house since February. Please send all information you have. Without help, financial and medical, I cannot survive...

A Connecticut attorney commented: I have been disabled by an illness with symptoms similar to those of CEBV. I have been forced to leave my job as a corporate attorney. I am too weak to resume work, even part time...

From Florida: I am certain I have this mysterious CEBV disease. My doctor can't help me. I am very anxious after 15 years of suffering to have hope of a cure...

...I am a 33 year old female who was previously a corporate vice president. I am now financially ruined from the costs of all I had to go through to get a diagnosis. In a few months when my corporate disability runs out I will lose my home and have no where to go. I am single and have no family who can take care of me. The frustration and anger and helplessness are almost unbearable...

From a flight attendant: After a year of being mis-diagnosed, I found a doctor who has been able to diagnose CEBV. I am 32 years old and find this virus disabling and distressing. I spend 5-10 hours in an enclosed environment and feel that the problem is widespread in the company. It is my doctor's feeling that I may eventually have to quit my career because of this illness...

One of the major concerns of CEBV researchers is the need to know more about patient distribution and the real numbers of those who are afflicted. To date, most of the effort to study the incidence of CEBV has come through the patients themselves, their support groups and in a study under the direction of Dr. Anthony L. Komaroff at Harvard Medical School.

In preparing for this Hearing, we contacted doctors who have been identified with CEBV research or treatment. Comments from these research physicians are excerpted from their letters:

James F. Jones, M.D., National Jewish Medical Center for Immunology & Respiratory Medicine, Denver, Colorado suggests the direction research should take:

1) Evaluate and define the CEBV syndrome. We must know appropriate diagnostic criteria for the syndrome and the patient distribution and numbers.

2) Look at psychological parameters of the illness. Patients complain of not being able to remember, to concentrate and therefore are unable to function on their jobs or in school.

3) Evaluation of sleep problems of patients. Preliminary data suggest that there are electrophysiological differences between these patients and other individuals during sleep.

4) Evaluation of why 80% of these individuals with CEBV have IgE-mediated allergy diseases.

5) Basic immunology should be studied. Are there differences among patients with this syndrome and other patients who have been exposed to the virus?

6) Evaluation of the virus. Is the virus in this syndrome different from the virus which apparently causes infectious mononucleosis?

7) Mechanism of reactivation. Are there factors such as stress, environmental factors...that may be of importance?

8) Therapeutic investigation must occur at the same time the above investigative procedures are being performed.

James C. Niederman, M.D., Yale University, Dept. of Epidemiological & Public Health, New Haven, Connecticut reports on CEBV research studies:

The objective of my ongoing research on chronic EBV infections is to characterize more precisely the syndrome of chronic infectious mononucleosis and to identify specific serologic markers for differentiations of latent asymptomatic EBV infection from chronic active symptomatic infection. We anticipate that the syndrome of chronic mononucleosis will likely include a heterogenous group of disorders. ...If functional protein defects could be unmasked in cases of chronic symptomatic Epstein-Barr infection, it might be possible to correct them through the therapeutic use of specific human immunoglobulin-containing antibody to the deficient protein.

Dr. Niederman continues: ...Dr. George Miller and I are studying patients with chronic mononucleosis and individuals with acute uncomplicated infectious mononucleosis, representing primary infection, as controls.

Irena, Brus, M.D., Clinical Medicine, Mt. Sinai School of Medicine, New York, New York commented: Ongoing molecular studies at Yale University are very promising in unravelling the mechanism of the disease. These researchers identified the genetic sequences responsible for latency transformation and viral replications -- a missing link in the understanding why the usually silent latent clinical state results in reactivation or chronicity. ...There is increasing evidence for a viral link between viral infections and certain types of autoimmunity. Epstein-Barr virus infection has been linked to certain cases of rheumatoid arthritis, SLE, and Sjogren's syndrome. Our proposed studies with Dr. Westley Reeves, The Rockefeller University Hospital, will examine the production of specific autoantibodies in patients with coexisting chronic EBV infection and collagen vascular diseases. The studies may provide information regarding the causes of autoimmunity and the pathogenesis of collagen vascular disease.

The question of 'how many are afflicted?' will not be properly answered as long as the patients themselves must seek ways of finding out this information. There must be a definite medical protocol set up at National Institutes of Health and/or Centers for Disease Control so that physicians will scientifically report the incidence of the chronic form of the Epstein-Barr virus in their patients.

We ask this Committee to recommend:

1) That the NIH, National Institute of Allergy and Infectious Diseases conduct more research on the chronic form of the Epstein-Barr virus infection in the search of better techniques for diagnosis, treatment, and an eventual cure.

2) That a protocol be established through:

   National Institutes of Health or
   Centers for Disease Control

   for reporting the incidence of the chronic form of the Epstein-Barr virus by physicians. This reporting should be set up as a clearinghouse of medical information to assist physicians, researchers and patients.

STATEMENT OF JAMES E. KENNEDY, D.D.S., PRESIDENT, AMERICAN ASSOCIATION OF DENTAL SCHOOLS AND DEAN, UNIVERSITY OF CONNECTICUT SCHOOL OF DENTAL MEDICINE

Senator WEICKER. Senator Proxmire will take over the chairing of these hearings. Before I leave, I would like to have the opportunity to have Dr. Kennedy come and testify.

Dr. KENNEDY. Thank you, Mr. Chairman. First, the American Association of Dental Schools [AADS] would like to thank you for the opportunity to present testimony previously for the Association of American Dental Research.

For my opportunity, I would like to highlight our concern for the funding of dental education. We believe that the limited funding provided to the health professions education in recent years will result in reduced access to the health professions for qualified students from nonaffluent backgrounds.

This Nation's dental services are not equally accessible to all. Abandoning Federal support of programs designed to recruit the best students without regard to socioeconomic backgrounds would undermine the progress we have made in the prevention and treatment of dental diseases.

The decline in Federal support for health professions education has paralleled an increased reliance on family financial resources to pay the costs of attending dental school. Dental students graduating last year came from families with median incomes 30 percent higher than the estimated U.S. median family income.

While blacks represent 12 percent of the U.S. population, they made up only 4 percent of the 1985 graduating class. Hispanics made up just 2.8 percent. This disparity will grow over the next few years unless resources are made available to address this problem.

While HCOP grants may be credited with keeping percentages of black and Hispanic students stable, actual enrollment levels of these minority groups have fallen since 1978. In addition, the disadvantaged assistance authorization includes an earmark for a new stipend program that is designed to provide grant support for the neediest students.

AADS would urge the subcommittee to fully fund the Disadvantaged Assistance Program. The Exceptional Financial Needs [EFN] Scholarship Program, which provides grants to first year students with zero financial resources is woefully underfunded. My own school is typical. Last year, three students qualified for EFN scholarship, but only one could be awarded. Qualified students from economically desperate backgrounds abandon hope of a career in dentistry when they learn that they will graduate with an average indebtedness of over $40,000.

Health professions educational assistance has also supported training in the delivery of services to geriatric patients. At Connecticut, we used a geriatric development grant to establish a clinical program for geriatric patients. Thus, seed money went to the permanent establishment of such a program.

General dentistry programs provide the skills and clinical experience necessary for the treatment of handicapped and other patients requiring specialized or complex care. Last year, only one-half of the approximately 23,000 graduates who sought advanced training in general dentistry could be accommodated. With modest investments, we could establish new residency positions which generally become self-supporting within a 3-year period.

The success of these educational programs is dependent on the availability of a well-trained faculty.

We would urge support for the dentist-scientist award as has been recommended by AADR. Mr. Chairman, since 1981, health professions education funding has declined by about 35 percent. These significant reductions have occurred at a time of increased demands on primary care training, recruitment and retention of disadvantaged students, and geriatric initiatives. AADS urges the subcommittee to fund the health education programs at the full authorized amount of $144.9 million.

Mr. Chairman, we would enthusiastically support the amendment we understand you intend to offer to restore health funding in the fiscal year 1987 budget. Senator Weicker, we appreciate your efforts on our behalf with the health program and would ask that you continue that support by inserting specific language as contained in our written report.

PREPARED STATEMENT

Mr. Chairman, the AADS appreciates your unfailing support of biomedical research, commitment to students, concern for the provision of exemplary care for those in need. We thank you for this opportunity to testify, and I would be pleased to respond to any questions that you might have.

[The statement follows:]

STATEMENT OF JAMES E. KENNEDY

Mr. Chairman and Members of the Subcommittee: My name is Dr. James Kennedy. I am Dean of the University of Connecticut School of Dental Medicine, and President of the American Association of Dental Schools (AADS), on whose behalf I appear today. This morning I would like to highlight the major areas of concern to our Association and, with the permission of the Subcommittee, submit a more detailed statement for the record.

AADS endorses the recommendation of the American Association for Dental Research with regard to FY 1987 funding for the National Institute of Dental Research. In the interest of time, I will not reiterate the statement of the AADR on NIDR appropriations. I would like to take this opportunity to highlight our serious concerns about funding for dental education.

We believe that the limited funding provided to health professions education in recent years will result in reduced access to the health professions for qualified students from non-affluent backgrounds. This nation's dental services are currently the best in the world but not equally accessible to all. Abandoning federal support of programs designed to recruit the best students - without regard to socioeconomic backgrounds - would undermine the progress we have made in the prevention and treatment of dental diseases.

The decline in federal support for health professions education has paralleled an increased reliance on family financial resources to pay the costs of attending dental school. This has adversely affected the heterogeneity of the dental school class. In 1978, the average dental student's parents had an income 12 percent higher than the United States median family income. Dental students graduating last year came from families with median incomes of $36,400--30 percent higher than the estimated U.S. median family income.

During this same time, the enrollment of Black students as a percentage of all enrollees has remained constant. While Blacks represent 12 percent of the United States population, they made up only 4 percent of the 1985 graduating dental class. Hispanic students made up just 2.8 percent of the 1985 graduates. The disparity between the number of minority students graduated from dental school and the number that would be required to achieve proportionate representation will grow over the next few years unless resources are made available to address this problem.

While Health Career Opportunity Program (HCOP) grants may be credited with keeping the percentages of Black and Hispanic students stable during the past several years, actual enrollment levels of these minority groups have fallen since 1978. These declines have serious implications for the population served by Black and Hispanic dentists. Recruitment and retention of qualified minority students will be compromised if program resources are inadequate.

In addition to HCOP grants, the Disadvantaged Assistance authorization includes an earmark for a new stipend program that is designed to provide grant support for the neediest students. Until this program was created last year, there was no grant money available to dental and medical students after their first year. AADS urges the Subcommittee to fully fund the Disadvantaged Assistance program, thereby providing $22.4 million for recruitment and retention projects and $5.6 million for disadvantaged student stipends.

The Exceptional Financial Need (EFN) scholarship program, which provides grants to first year students with zero financial resources, is woefully underfunded. My own school is typical. Last year, three students qualified for the EFN scholarship, but only one could be awarded. Qualified students from economically desperate backgrounds abandon hope of a career in dentistry when they learn that they will graduate with an average debt of over $40,000. The EFN program helps these students get started. Our Association recommends full funding of $7 million for the coming year.

Health professions educational assistance has also supported curricular and training initiatives responsive to the changing needs of society. Training in the delivery of health services to geriatric patients is essential if this generation of dental students is to be prepared to treat elderly patients. At Connecticut, we used a federally-funded geriatric development grant to expand the curriculum and establish a clinical program for geriatric patients. The grant spurred initiation of the program which made it possible for the school to become the dedicated dental provider for an affiliated 260 bed geriatric hospital and an outpatient service that treats 160 patients per day. Thus, seed money from federal funding ultimately led to a permanent program. AADS urges the Subcommittee to fund geriatric and special care initiatives at $8 million for FY 1987.

General Dentistry programs provide the skills and clinical experience necessary for the treatment of handicapped and other patients requiring specialized or complex care. Demand for this primary care training continues to be extremely high. Last year, only about one-half of the 2,000 dentists who sought advanced general dentistry training were accommodated. Past federal support has been vital to the establishment and initial maintenance of these residency positions. A modest investment will allow the creation of new residency positions, which generally become self-supporting within three years. Accordingly, we recommend an appropriation of $2.8 million in FY 1987 for this important effort.

The success of these educational programs is dependent on the availability of a well-trained faculty. Funding of the Dentist-Scientist Award, as urged by AADR, is essential to generation of new knowledge and the transfer and application of this information to patient care.

Mr. Chairman, since 1981 health professions education funding has declined $38 million. When adjusted for inflation, this represents a 35 percent decrease! These significant reductions have occurred during a time of increased demands for primary care training, recruitment and retention of disadvantaged students, and geriatric initiatives. As illustrated by the several programmatic examples contained in this testimony, health professions training assistance provides funding critical to the recruitment and retention of a heterogeneous, well-qualified cadre of dental students able to deliver primary care to the nation. AADS urges the Subcommittee to fund health professions education programs at the full authorized amount of $144.9 million*.

Although the Health Education Assistance Loan (HEAL) program requires no Federal outlay, our Association is very concerned that the program remain a viable "loan of last resort" for dental students. Students pay the market rate for these unsubsidized loans and are assessed an insurance fee to offset defaults. Last year, approximately 4,600 dental students borrowed over $47 million through the HEAL program to finance a portion of their dental education. Even though the cost of the HEAL program is borne entirely by participating borrowers, the Administration has repeatedly tried to terminate or significantly restrict access to this program.

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*This amount does not include $21.5 million recommended to maintain a current services level for direct operations or $2 million for Analytical Reports which make up the remainder of the Health Professions Training activities.

Senator Weicker, we are most appreciative of your efforts on behalf of the HEAL program, and we ask the Subcommittee's assistance again this year to assure continued access to the HEAL program by inserting language in the FY 1987 appropriations bill that will address the following concerns:

1. Access to HEAL loans should be guaranteed up to the authorized limit of $290 million plus any unused amount carried over from prior years. Unless this is specified in the appropriations bill, we believe that the Administration will again restrict credit availability. Limiting HEAL credit would cause a "free-for-all" among schools attempting to secure adequate credit for their students.

2. The total amount of HEAL credit authority should be required to be granted without apportionment or other similar limitations. This language is necessary to prevent the Office of Management and Budget and the Department of Health and Human Services from delaying release of HEAL credit by administrative maneuvering.

3. The Department of Health and Human Services should be directed to issue the proposed regulation on the HEAL program immediately. This rule will tighten program administration and loan collection requirements, thereby lowering HEAL defaults.

   Much concern has been expressed about defaults on HEAL loans. AADS has made correction of student loan defaults a top priority. I am pleased to report that Representatives of our Association and from the American Dental Association have formed a task force that will work with officials from the Department of Health and Human Services to develop strategies for prevention and reduction of HEAL defaults. When our schools tackled the delinquency problem for the Health Professions Student Loan program, we reduced the delinquency rate to below 4 percent nationwide. We are confident that, working with schools, lenders and the Administration, a significant improvement can also be achieved in the HEAL program.

Mr. Chairman, AADS appreciates your unfailing support of biomedical research, commitment to students, and concern for the provision of exemplary patient care to those in need. We thank you for this opportunity to testify on the FY 1987 appropriations. I would be pleased to respond to any questions you may have.

Senator WEICKER. Dean Kennedy, I think that you bring up a whole new area, which you bring up in the sense of dental schools, but it could be applied right across the boards, and that is this matter of personnel. By personnel, I mean teachers; by personnel, I mean those that are going to go into the medical professions; by personnel, I mean those that are researchers.

This whole area, also, has been woefully underfunded, and I feel we are going to pay a real price in the future. Just that little small area you mentioned about geriatric care of the teeth. My God, we are not prepared in any sense of the word to handle the geriatric problem that is coming over the hill at us.

Dr. KENNEDY. And the long-term costs of that will be coming at us, too. We don't have manpower to handle those problems. We know they are coming.

Senator Weicker. Thank you for your testimony, Dr. Kennedy.

Senator Proxmire?

Senator PROXMIRE. Dr. Kennedy, let me ask you one question. The chairman has been a tremendous champion of your program. I think it has a great deal of merit. However, I understand, and perhaps I am mistaken, that there is an oversupply of dentists now. If, therefore, we make it easier for more people to go to dental school, aren't we just contributing to the oversupply? Or is that a misapprehension?

Dr. KENNEDY. Let me answer it this way. I think we established a system of manpower in the early seventies and eighties. I think you have seen a steady decline in enrollment in dental schools. Dental schools have reduced their first year enrollments by about 1,400. If you assume 100 students per first year, that is the equivalent of about 14 schools.

I think my concern at this point is that while schools put their efforts to continually identifying well-qualified applicants, we at the same time allow those well-qualified applicants to come from all segments of our society. I think it is critical; it is important to us to be sure that all segments have access to care.

I don't think there is an excess in the sense that individuals are not able to practice their profession. I think the unfortunate things is if there is reserve productivity within that manpower pool, it is not being available to the broader segments of the population.

Senator PROXMIRE. I appreciate your response very much. Then it is your conclusion that if we do increase dental school funding, it will not contribute to an oversupply of dentists, but it will allow better qualified people, and particularly people from various groups who are not well represented in the dental profession, to enter the practice of dentistry.

Dr. KENNEDY. Exactly.

STATEMENT OF ALFRED A. BAUMEISTER, PH.D., DIRECTOR, JOHN F. KENNEDY CENTER, AMERICAN PSYCHOLOGICAL ASSOCIATION, AMERICAN ASSOCIATION ON MENTAL DEFICIENCY, AMERICAN ACADEMY ON MENTAL RETARDATION

Senator PROXMIRE [presiding]. Our next witness is Dr. Alfred A. Baumeister, Ph.D., director of the John F. Kennedy Center, American Psychological Association, American Association on Mental Deficiency, American Academy on Mental Retardation

Senator PROXMIRE. Dr. Baumeister, we are very glad to have you here. It sounds like a Wisconsin name.

Dr. BAUMEISTER. It could be, but it is a Alaskan name.

I am director of the John F. Kennedy Center, and this is 1 of the 12 national research centers. I am representing the American Association of Mental Deficiency, the American Academy on Mental Retardation, and the American Psychological Association. We are grateful for the opportunity to present our views, and we are particularly grateful for the support this committee has demonstrated relative to its concerns for research.

I want to talk specifically, though, about mental retardation and in relation to NICHD. There are well over 200 conditions associated with mental retardation including genetic problems; problems of pregnancy and birth, brain damage due to a large number of teratogens, problems of accidents and other circumstances of poverty, undernutrition, and lack of adequate stimulation.

We emphasize that even in those cases in which we have knowledge as to cause, we know precious little about how to prevent or cure. Despite advances in understanding mental retardation, the truth is that in most cases, we do not know what causes it or how to prevent it.

To cite an amount, amniocentesis is not a preventive measure in the ultimate sense for Downs syndrome. Fetal alcohol syndrome is a condition that is virtually an epidemic in this country, and we do not have adequate measures in place to prevent it.

One fact should be made clear: Most mental retardation cannot be traced to specific biomedical causes. We are dealing here with health problems whose primary manifestations are behavioral in nature.

I heard earlier testimony that the infant mortality rate in this country is high. Actually, the infant mortality rate for this year showed and increase for the first time since the end of World War II.

Along with the increase in infant mortality rate is an increase in morbidity. That, in prevalence of the new morbidity, primarily reflected in behavioral disorders, is increasing, as well. The human and financial cause associated with mental retardation are straggering.

No other human affliction creates so much suffering at such great cost for so long to the family, the community, and our Nation. Consider just 130,000 people right now who are in public institutions. We will spend over $4.5 billion this year. We will spend another $4.5 billion in community-related services.

The cost of education of a retarded child in the public schools is several times that of a normal child. In 1985, NICHD expended $44 million on mental retardation research, about 14 percent of their budget. We do not believe that this is a level of response consistent with either: *a*, congressional intent in creating the NICHD; or *b*, severity of the problem of mental retardation in human and financial terms.

It is also evident that what is accounted as mental retardation is not directly relevant to mental retardation. In 1985, NICHD obligations came to $309 million, approximately. The 1986 appropriation for the Institute was $322 million. However, in 1986, subsequent to cuts, the actual amount was $307 million. Now the administration proposes a budget of $309 million, less than in 1985 and certainly less than what Congress appropriated.

Through the magic of Gramm-Rudman, such reduction is possible, of course. This year, the average reduction in grants was 14 percent, not 4.3 percent, in NICHD. Cuts of this magnitude hurt people, children, mothers, families, and the question must be raised: Is this what we intend by way of public policy?

This is not an arbitrary budget consideration that will merely inconvenience a few people. Continued cutbacks on health research are shortsighted, very costly, and constitute a grievous disservice to millions of Americans of health, well-being, and the quality of life which governments should respond to.

PREPARED STATEMENT

In my written testimony, I have listed at the end a number of recommendations concerning funding measures that we hope this committee will consider and adopt. Thank you.

[The statement follows:]

STATEMENT OF ALFRED A. BAUMEISTER

Mr. Chairman, my name is Alfred Baumeister. I am the Director of the John F. Kennedy Center at Vanderbilt University, one of the 12 national Mental Retardation Research Centers constructed and established under the provision of Public Law 88-164. Appearing here today I represent the American Association on Mental Deficiency, the American Academy on Mental Retardation, and the American Psychological Association. These are all professional organizations dedicated to solution of the problems of mental retardation and related disabilities. We are grateful for the opportunity to share our views concerning federal support, through NICHD, for research on mental retardation and related disabilities.

Mental retardation is a life-long disability with social, psychological, and biological causes. The principal manifestations are subaverage intelligence, significant impairments to learning and to social and physical development, and diminished ability to live independently. Well over 200 different causes are associated with mental retardation, including genetic conditions, disorders of metabolism, problems of pregnancy and birth, brain damage due to a large number of teratogens, accidents, and other untoward circumstances that affect development, such as poverty, undernutrition, and lack of adequate psychological and social stimulation. But we must emphasize that even in many of those cases in which we have some knowledge as to cause, we know precious little about how to prevent or cure.

The human and financial costs to society of mental retardation and the other developmental disabilities are staggering. No other human affliction creates so much suffering, for so long, and at such great cost to the individual, the family, the community, and our nation. There are approximately 6,600,000 retarded persons in the United States today and about one out of every 6 or 7 families is directly affected. To provide care and habilitation to the 130,000 retarded persons who reside in public institutions, we will spend over $4.5 billion this year. The average cost is more than $1 million over the life time of each severely retarded individual. In 1984 the average rate across this country to care for a retarded person in an institution exceeded $100 per day. Another example: approximately 4,000 babies will be born this year with fetal alcohol syndrome. These babies will be severely retarded and most of them will require complete public assistance throughout their lives. Basing my calculations on these facts I can conclude that this group of FAS babies alone, born in just this year, will require over $4 billion for lifetime care.

The cost of education of a retarded child in the public schools is several times the amount expended on the education of a nonretarded child. The variety of special programs in the community that must be provided for our retarded citizens represents an enormous outlay as well, also now running about $4.5 billion annually and increasing.

The costs in terms of human suffering and in lost human resources and potential are beyond financial calculation. We must remember that mental retardation and the other developmental disabilities, if uncorrected, typically persist over a life time and that many thousands of babies will be born in this decade who will never have a chance, for even part of their lives, to share in the ordinary opportunities and challenges that we here enjoy.

Because the Congress has responded to the need, we have made enormous scientific progress over the past two decades toward the twin goals of prevention and amelioration of mental retardation. Much of this knowledge has been put into practice with outstanding results. For example, we now understand the biochemistry underlying some specific genetic disorders and, through proper intervention, are now able to create medical and environmental conditions where people who only two decades ago would have been profoundly retarded are now able to live normal lives. Studies of behavior and social processes have enabled us to develop effective educationally based procedures that ameliorate many of the learning and behavior problems associated with mental retardation. We have also learned a great deal more about causes of mental retardation, knowledge that can have enormous significant public policy implications. For instance, public policy has followed from the empirical demonstration that environmental exposure to lead can cause a continuum of biological and behavioral risks ranging from very severe to mild in form. Similarly, significant implications are inherent in the now convincing experimental and descriptive data showing that alcohol and other drugs are teratogens that can have devastating effects on the developing fetus.

Over the past few years a variety of exciting new behavioral and biomedical concepts and techniques have been incorporated into the study of mental retardation, such as the role of peptides and neurotransmitters in the functioning of the nervous system, sophisticated quantitative techniques for the study of neuropathology and neuroanatomy, the introduction of new cytogenetic procedures, the discovery of new methods for analysis of plasticity of behavioral development, improved understanding of how environments and biology interact, and new methods for promoting generalized learning and transfer of skills from one context to another.

Yet we cannot become complacent because, despite advances in our understanding of mental retardation, and therefore, in our ability to intervene effectively, the truth is that in most cases we do not know what causes the retardation, or how to prevent it. One fact should be made clear--the source of mental retardation in most cases cannot be traced to a single specific biomedical cause.

Most mental retardation, between 70 and 80% of the cases, is linked to psychosocial disadvantage. In 1984, 14.4% of our population, including 21% of our children were below the poverty line. But, as you are aware, minority groups are differentially represented.

According to the government's own 1984 data, 46% of black children and 39% of Hispanic children lived in poverty. These are families who are located in the lower end of the socioeconomic scale. But consider another factor, one most grim and one that portends serious consequences for this nation. Whereas poverty among the elderly was recently a major social problem, this group of Americans now enjoy a better quality of life than ever. Poverty has virtually disappeared among the elderly; but there is age bias associated with poverty and it is the children who are its victims. Consider the following 1984 data for poverty rates: 24% among preschool children; 20.3% among school-age children; 11.7% among adults, non-elderly; 12.4% among the elderly. Poverty is not a wholesome condition for rearing children. Mental retardation does not cause poverty, but poverty contributes to mental retardation, at all degrees. We need to know more about how biological vulnerability interacts with environmental circumstance to produce mental retardation. Much more research must be addressed to this most fundamental issue.

One of the most consistent relationships in the literature is that between socioeconomic status and behavioral adaptation. The correlations between these two general factors are large in every modern industrial society. Incidence rates of mental retardation and mental illness appear to be five and six times greater, respectively, in the lowest as compared with the highest SES level.

Why is socioeconomic status associated with mental retardation and emotional disturbance? What are the implications for prevention? These are important questions, ones that have been addressed before but not systematically and intensively. Their resolution is anything but clear. One fact emerges from an analysis of the relevant literature, much of it of fairly recent origin. Environment, including family background, plays a more significant role than biomedical factors in determining developmental outcome, even among neonates with medical problems. While it is true that some retarded people suffer from identifiable neuropathology, the vast majority do not. The studies before us show that, except for severe handicaps at birth, dysfunctions as defined by the "New Morbidity" are more strongly predicted by family variables and SES than by biological factors. Prevention strategies will have to be based upon environmental considerations.

The relatively high risk of mental retardation and psychiatric disorder in lower SES groups is best characterized by a transactional process in which certain children are psychologically and biologically vulnerable to environmental and social variations that predispose them to school, economic, and social failure--the "New Morbidity".

I can tell you something more about this relationship. The environments in which economically deprived children develop are less conducive to good physical, social and behavioral development than are the environments of children not so disadvantaged. These differences are deep rooted, fundamental, enduring, and intergenerational, a fact that has not received sufficient attention and respect, either by researchers or practitioners. As group, mothers of such children are not so well nourished, they are smaller, and they received less nuturing care as children themselves. When they have their own children they are younger (frequently teenagers) and they have children more often. When she is pregnant, the general health of a woman at the low SES range will be poorer than that of a woman who is better off and her fetus will be exposed to greater risk of infection, intoxication, and trauma. Prenatal and general health care are less accessible to her, a condition that appears to be growing even more serious owing to recent cutbacks in health care programs. Today she is far less apt to be married than her richer sister and thus more vulnerable to a number of threats to good child rearing practices. Babies of such mothers, on the average, when they are born, are smaller for gestational age, are more likely to be premature, die more readily and more suddenly, are sicker in infancy, suffer a higher rate of accidents, and run a greater risk of neglect than children born into better circumstances. Their mortality is excessively high at birth and beyond; their illnesses more frequent, more persistent, and more severe. Their development is a function of maternal health, age, income level, education, habits, and social milieu. During the school years, nutrition may be inadequate, the children may miss school more frequently, and housing is frequently substandard. They will present a higher rate of learning problems, behavior disturbances, allergies, and speech difficulties. Such terrible problems will not yield to insular, simplistic, and cosmetic solutions.

Yet, since 1974, the commitment to mental retardation research has deteriorated. For ore than 10 years my colleagues and I have conducted various types of analyses of NICHD funding patterns with particular reference to the status of mental retardation as a funding priority within NICHD. The one general and compelling conclusion emerging from these analyses is that funding for mental retardation research, both in absolute and relative terms, is in a much less favorable position today as compared with its status 12 years ago. In 1986 dollars, our research capability is less than half what it was in 1975. Core support funding for the 12 national Mental Retardation Research Centers has been severely eroded. Attached is a table that shows a regular and continuing decline in relative support for mental retardation research, from 1972 to 1985. This table is based on the budget of the NICHD's Center for Research on Mothers and Children (CRMC). This is the organizational unit that carries the NICHD obligation to support mental retardation research.

In 1985, NICHD expended a total $44 million on research projects dealing with mental retardation, out of a budget of almost $310 million, about 14%. We do not believe that this is a level of response consistent with either: (a) Congressional intent in creating the NICHD, or (b) the severity of the problem of mental retardation in human and financial terms. It is also clear that much of what is counted as "mental retardation" research is not clearly relevant and that a large proportion of the Institute's budget is directed at basic biomedical and behavioral research that has little or no relation to solving problems of mental retardation or closely related insults. The Congress must insist that the Institute demonstrate relevance of its support to the problem of mental retardation.

In 1985, NICHD obligations came to a total of $309,823,000. The 1986 appropriation for the Institute was $322,282,000, an increase of about $12 million, or 4%. However, in 1986, subsequent to sequestering and revision, the actual amount was $307 million, a decrease from the previous year. Now the Administration proposes a budget of $309,119,000 for NICHD, an amount less than in 1985 and certainly substantially less that what Congress appropriated in 1986.

Through the magic of the Gramm-Rudman-Hollings bill such reductions are possible, because the arithmetic is impeccable. For this year the average reduction in grants was 14% at NICHD. But cuts of this magnitude hurt people--children, mothers, families--and the question must be raised: is that what we intend by way of public policy? The people and the organizations I represent are distressed over these events that affect not only NICHD but all of NIH. This is not some arbitrary budgetary consideration that will merely inconvenience a few people. Continued cutbacks of health research capabilities are short-sighted, ultimately very costly, and constitute a grievous disservice to millions of Americans whose health, well being, and quality of life depend on this government to respond to genuine need.

RECOMMENDATIONS

Expenditures for research related to mental retardation have declined steadily both in relation to inflation and as a proportion of the relevant program within NICHD. Therefore, our first major purpose is to assure continued support for mental retardation research and to reverse the decline in funding.

We respectfully encourage the Congress to increase appropriations to NICHD to a level that, at the minimum, ensures the continuity of research and research training programs and at a level that begins to reduce the decline in funding for mental retardation research about which we spoke earlier. We believe that this can be done in two ways: First, the Congress should provide for an increment in the NICHD budget adequate to offset the cumulative effects of inflation and to accelerate the effort in mental retardation research. Second, and more specifically, you should specify that mental retardation research should be elevated as a priority.

My colleagues and I also request that some of the implications of the information presented in our comments be reflected in the narrative report language. We believe that improvement of mental retardation services depends on excellent basic behavioral and biological research in the areas of prevention, early diagnosis and intervention, learning, and long-term care. Most important, because mental retardation is a constellation of behavioral phenomena with numerous biological and psychosocial causes, collaborative research programs incorporating behavioral and biological components should be fostered. We urge:

1. The Congress to increase funding to NICHD from $307 million in the current fiscal year to $376.7 million in fiscal year 1987, an increase of about 23%. This is in contrast to the Administration request for $309.1 million for fiscal year 1987.

2. The Congress to mandate that at least 25% of the extramural support of NICHD be for projects directly relevant to mental retardation.

3. That the Mental Retardation Research Centers be designated as a special item in the budget.

4. The Congress to express its commitment to the continuation of high-quality predoctoral and postdoctoral research training by increasing funds in this category by 10%.

5. That the Congress ask NICHD to demonstrate that the mental retardation research supported by that Institute is truly and directly relevant to prevention and treatment of mental retardation and associated disorders.

6. That funds be transferred from NIMH to NICHD to support research on people who have the dual problem of mental retardation and mental disturbance.

NICHD Trends in MR Funding*
(Millions of Dollars)

Year	Total CRMC Funds	Total CRMC-MR	MRDD	MRRC Core
972	42,838,000	21,365,000	17,250,000	5,856,000
1973	41,971,000	21,330,000	16,642,000	6,533,000
1974	51,894,000	23,886,000	18,096,000	5,761,000
1975	55,094,000	25,420,000	18,884,000	5,672,000
1976	60,161,000	27,016,000	20,423,000	5,603,000
1977	64,979,000	28,419,000	21,434,000	6,166,000
1978	73,790,000	30,298,000	23,318,000	6,455,000
1979	102,492,000	35,321,000	28,121,000	6,759,000
1980	101,154,000	34,731,000	27,559,000	6,751,000
1981	106,055,000	32,997,000	26,969,000	6,623,000
1982	105,530,000	31,768,000	25,963,000	6,549,000
1983	123,346,000	35,270,000	29,306,000	7,343,000
1984	135,489,000	35,699,000	29,263,000	7,737,000
1985	157,727,000	44,329,000	36,365,000	9,298,000

Percents of Total CRMC

1972		50	40	13.7
1973		51	40	15.6
1974		46	35	11.1
1975		46	34	10.3
1976		45	34	9.3
1977		44	33	9.4
1978		41	32	8.7
1979		34	27	7.0
1980		34	27	6.7
1981		31	25	6.2
1982		30	25	6.2
1983		29	24	6.0
1984		26	22	5.7
1985		28	23	5.9

*Source of Data: NICHD, Office of Planning and Evaluation

CRMC = Center for Research on Mothers and Children

MR = Mental Retardation research

MRDD = Mental Retardation/Developmental Disabilities Branch in the CRMC

MRRC Core = Mental Retardation Research Centers (Public Law 88-164) core support

Senator PROXMIRE. You made the startling observation that last year was the first year since the end of World War II in which infant mortality in America increased.

Dr. BAUMEISTER. Yes.

Senator PROXMIRE. On page 2 of your prepared statement you say, "Significant implications are inherent in the now convincing experimental and descriptive data showing that alcohol and other drugs are teratogens that can have devastating effects on the developing fetus."

Dr. BAUMEISTER. Yes.

Senator PROXMIRE. Is this, in part, because of increased drug use?

Dr. BAUMEISTER. That is partly it, sir. We have also discovered a great deal about the nature of fetal alcohol syndrome. There will be about 4,000 babies born this year who have full blown fetal alcohol syndrome, but that is the tip of an iceberg, because a lot of babies will be affected by alcohol consumption of the mother.

I asked the question: Is the right of the fetus to develop in a wholesome environment less absolute than the right of the parents to behave in ways to endanger that fetus? I think therein lies a moral and ethical question, as well.

Senator PROXMIRE. That is fascinating.

In point No. 6, you suggest that funds be shifted from the National Institute of Mental Health.

Dr. BAUMEISTER. Yes.

Senator PROXMIRE. Do you feel the Institute is not capable of supporting quality research in mental retardation?

Dr. BAUMEISTER. What has happened is a large number of mentally retard people present the dual model. It is not what we expect of the population at large. The National Institute of Mental Health [NIMH] and NICHD have not produced the type of research systems that are necessary to address that dual problem. It is a problem that has fallen right between the cracks.

Last year, I participated in a conference that was hosted by the President's Committee on Mental Retardation where we addressed that issue. Basically, the recommendation that came out of that conference was that funds be transferred from NIMH to NICHD to enable that kind of research to be conducted because it is a serious problem, and sir, I would say that it is one of the factors that is contributing to institutionalization. If there is any reason that is given for institutionalization now, it has to do with the problem that many retarded people exhibiting extreme behavior disorders, as well, effectively have disorders.

Senator PROXMIRE. Thank you very much. You are at Vanderbilt, is that right?

Dr. BAUMEISTER. Yes, sir.

Senator PROXMIRE. That is a superb institution.

Dr. BAUMEISTER. They will be grateful to hear that.

Senator PROXMIRE. I think the world of it.

STATEMENT OF MICHAEL S. TEITLEBAUM, CHAIRMAN, PUBLIC AFFAIRS COMMITTEE, POPULATION ASSOCIATION OF AMERICA

Senator PROXMIRE. The next witness is Michael S. Teitlebaum, chairman, public affairs committee, Population Association of America [PAA].

Senator PROXMIRE. Mr. Teitlebaum, we are delighted you are here.

Mr. TEITLEBAUM. Thank you, Mr. Chairman. It is very nice to be back on the Hill.

Senator PROXMIRE. You have been here before?

Mr. TEITLEBAUM. Yes, sir; I was the staff director of the House Population Committtee in the seventies. We got over to this side of the rotunda a few times during that period.

Mr. Chairman, it is a great pleasure to be here. I am the chairman of the public affairs committee of the Population Association of America, and I appreciate the opportunity to speak to you. I would like to take the opportunity to compliment you, in particular, Mr. Chairman, on your continuing emphasis upon the need for preventive health attention and clear-eyed foresight of health needs as they develop in this complex population in the United States.

I am appearing on behalf of the Population Association of America, which is the professional scientific society of some 2,600 demographers and others involved in the scientific research on population. PAA members receive research support from many sources, and their services are increasingly in demand from private industry and Government, but an important funding source for their research is through the Center for Population Research at NICHD.

The demographic facets of population research provide unique health-related information that assists national, State, and local governments in making the kinds of difficult allocation decisions that bedevil the U.S. Congress on a day-to-day basis, and I am sure you appreciate how bedeviling those are.

Major factors affecting the needs for allocation and reallocation are the size and age composition, the geographic distribution of the population. These are of critical importance to policymakers such as yourself, Mr. Chairman.

For example, a previous witness in discussion with Chairman Weicker concerning the future needs for geriatric care, a perfect example of wholly predictable trends that will vex this body, I predict, over the next 50 years: How to provide decent health services to growing numbers of geriatric patients and the evidence from this comes from high quality fundamental demographic knowledge and demographic data collection.

Another example that you will have contended with over your long career in the Senate is the unexpected surge of births, the so-called baby boom post-World War II, a prime example of a demographic phenomenon that was certain to reverberate throughout the society. These baby boomer, and I am on the leading edge of the baby boom myself and watch them behind me, they seem to be following me as I went up through my life, they crowded first the maternity wards; then the public school systems; then they boosted the enrollment colleges and universities and enhanced the ability of the economy to absorb work forces.

As they enter the economy, they expand into infrastructures and they force an expansion and then the pain of contraction. Anybody dealing with the opening and closing of local schools boards know how painful that process is. The fact is, had the local policymakers been more attentive to demographic research of the 1950's and 1960's, they would have known more about these population dynamics, which in many cases were more predictable and predicted they would have been better anticipated and planned for.

The financial savings, Mr. Chairman, would have been truly enormous. We are talking in the billions, maybe hundreds of billions of dollars across all the State and local agencies that finance the building of new schools that, in many cases, turn out to be surplus now.

Another example, Mr. Chairman, is the changing patterns of marriage and divorce, living arrangements, remarriage, and, once again, demographic research is providing very important information that is a critical utility to public and private sectors.

As evidence of that, I would simply report to you, Mr. Chairman, that virtually every large corporation in the United States now is fully aware of the significance of demographic change. They call it demographics, and they have become heavy consumers of demographic data and demographic research.

Mr. Chairman, it is important to note there is no problem of oversupply of demographers in the the United States. To the contrary, there continues to be a shortage which is not being met by the available teaching facilities.

The primary source of Federal funding for demographic research comes from within NICHD, the Center for Population Research. For fiscal year 1986, Mr. Chairman, of the $322 million appropriated for NICHD, the Center for Population Research overall, which is heavily biomedical, of course, in its orientation, received approximately $106 million. The demographic and behavioral sciences branch of the budget represented only one-sixth of this $106 million.

I will not repeat to you the request of the President for 1987. You have heard that from many other witnesses, but I would simply say that this reduced request comes at a time when NICHD is in the forefront in studying some of the most critical issues facing our country: The causes and implications of low birth weight, which will affect the work of all committees of the Senate and the House; birth defects and genetic disease; mental retardation; unintended pregnancies and development of new, safer, and more acceptable methods of contraception, all of them very prevention oriented, Mr. Chairman, as you can appreciate.

The Population Association of America urges this subcommittee to support the original request of the Institute to the Department of

Health and Human Services, $376 million for fiscal year 1987. This level would put NICHD on a parity with other institutes in relation to the funding rate for competing research grants.

In 1986, NICHD had an award rate of only 26 percent, meaning only 26 percent of those projects which were approved were actually funded. Awards for other institutes averaged 34 percent. The highest rates were 50 percent at the National Eye Institute and 42 percent at the National Institutes of Dental Research to the lowest rate at the National Institute of Child Health and Human Development.

Mr. Chairman, if I may diverge for a personal comment, I believe this bespeaks an insufficient attention to the principally preventive aproach of the NICHD vis-a-vis many of the other institutes at NIH, and I was at one time an employee of the National Cancer Institute and have a great appreciation for the work of that Institute. But it is, nonetheless, true that the NICHD is one of the most prevention oriented institutes at NIH.

One last word, Mr. Chairman. My time is up. It has to do with the training programs of NICHD. I have already reported to you there is no surplus, there is a shortage, indeed, of well trained demographers in the United States. The demands are increasing. I frequently receive, I would say, every 2 weeks coming across my desk a recruiting letter from a corporation or a Government agency looking for a well-trained demographer. This is a small area of the budget, but it is not a discipline that has been in oversupply.

PREPARED STATEMENT

May I close, Mr. Chairman, by again urging attention to the preventive health needs of the U.S. population which can be greatly assisted by high quality demographic research, which is probably the fundamental source of foresight and intelligence about what the future needs will be.

Thank you for your time.

[The statement follows:]

STATEMENT OF MICHAEL S. TEITLEBAUM

Mr. Chairman and Members of the Subcommittee on Labor, Health and Human Services and Education of the Senate Appropriations Committee, I appreciate the opportunity to speak to you today regarding the appropriation for the National Institute for Child Health and Human Development (NICHD), for Fiscal Year 1987.

I appear before you today on behalf of the Population Association of America (PAA). This is the professional research society of some 2,600 demographers, economists, geographers and sociologists, indeed PAA represents all those involved in scientific research on population. Research in this broad area ranges widely, from identifying the factors that affect Americans' child bearing decisions to exploring the impact of energy costs on interregional migration. While PAA members receive research support from many sources, an important funding source for demographic research comes through the Center for Population Research at NICHD.

Demographic and behavioral facets of population research provide unique information that assists national, state and local governments in making often-times difficult allocation decisions. The size, age composition, geographic distribution of the population are of critical value to policymakers in many diverse areas. The unexpected surge of births that spawned the so-called baby-boom is a prime example of a demographic event that from its onset was certain to reverberate through the society. Baby-boomers crowded maternity wards, the public school system, boosted enrollments in colleges and universities and taxed the ability of the labor force to absorb cohorts of unprecedent size. Passing through its life cycle, the baby-boom generation strained existing infrastructures, forcing first their rapid expansion and then their contraction. Had public policymakers been more attentive to demographic research these population dynamics could have been anticipated and planned for. The financial savings would have been truly enormous.

By studying trends and variations in fertility, demographers are working towards a clearer understanding of the factors that affect child-bearing, the social and economic consequences of changes in birth rates and changing family structure. All of these demographic trends have important policy implications. Researchers are concentrating special efforts on the problem of adolescent pregnancy, by studying the fertility behavior of teenagers and by examining the consequences of adolescent childbearing both for the individuals involved and for state and federal programs and expenditures.

Demographic studies also document the changing structure of the American family by exploring factors underlying the timing of first marriage, the incidence of divorce, living arrangements, remarriage trends, and morbidity patterns. In its scrutiny of the social and economic implications of population growth, decline and change, demographic research provides invaluable analyses for effective planning in both the public and private sectors. By now, virtually all large corporations are aware of the significance of demographic change, and have become heavy consumers of demographic data and research.

The primary source of federal funding for demographic research is within NICHD -- the Center for Population Research, the Demographic and Behavioral Sciences Branch. This Branch supports a program of research which responds to changing social conditions as well as to the developing base of basic scientific knowledge. Currently a major focus of the program is the examination of family and household structure and its impact on the well-being of children. For example, empirical evidence indicates that marital status and living arrangements have a direct impact upon economic well-being. Findings from this research show that when marital dissolution occurs women and their children experience a drop in income levels. In fact, approximately one-fourth of the children who experienced the dissolution of their family fell into poverty as a result. Another research effort underway is examining contraceptive use among adolescents -- who uses it and who uses it well. Other research projects related to adolescent pregnancy have studied the relationship between postponement of child-bearing and the resulting benefits to individuals and society. Related research is assessing the effects of teen parenthood on school-related accomplishments and on the social and emotional adjustment of their offspring. Two studies have found a consistent tendency for children of adolescents to have slightly lower I.Q. scores than children of older mothers when measured at several ages up to seven years, and some effects of maternal age on social and emotional development have also been found. The work of this Branch is an important complement to the total research mission of the National Institute of Child Health and Human Development.

For Fiscal Year 1986, of the $322 million appropriation for NICHD, the Center for Population Research received approximately $106 million. The Demographic and Behavioral Sciences Branch's budget represents only one-sixth of this amount.

For Fiscal Year 1987 the President has requested only $309 million for NICHD. This reduced request comes at a time when NICHD is in the forefront in studying some of the most critical issues facing our country: the causes and implications of low birth rates, birth defects and genetic disease, mental retardation, unintended pregnancies, and development of new, safer and more acceptable methods of contraception.

The Population Association of America urges this Subcommittee to support the original request of the Institute to the Department of Health and Human Services -- $376 million for Fiscal Year 1987. This level would put NICHD on a parity with other Institutes in relation to the funding rate for competing research grants. For Fiscal Year 1986 NICHD had an award rate of 26 percent, meaning only 26 percent of those projects which were approved were actually funded. Awards for other Institutes averaged 34% with the highest rates of 50% at the National Eye Institute and 43% at the National Institute of Dental Research to the lowest rate at the National Institute of Child Health and Human Development. This has happened at a time when NICHD has experienced a significant increase in the number of grants approved. The $376 million appropriation level would also restore training positions to the Fiscal Year 1985 level, permit funding for two additional centers focusing on prevention of premature births and would continue to support the Institute-wide initiatives on Low Birth Weight and Infant Mortality and Contraceptive Development.

One important function of NICHD is the administration of its training programs at various universities. These programs have encouraged and enabled many researchers to enter the field. In recent years the government has reduced the level of funding provided for this purpose, and the 1987 budget request would represent a further decline in support. The PAA endorses NICHD's original budget request which would restore the level of funding for training to its 1985 level. It is important to note that there is no surplus of well-trained demographers, whose skills continue to be in high demand in industry, universities, and government.

Our recommendation for this appropriation level reflects our support for the full range of research activities at the Institute. We believe the breadth of research encouraged by NICHD provides a cost-effective investment in the future of our children, and furthers our understanding of complex demographic processes of central and growing importance to policymakers.

Senator PROXMIRE. Dr. Teitelbaum, you have the advantage, as a witness, of having served on the Hill, and you understand how the Congress works very well.

Mr. TEITLEBAUM. I am not sure I understand. [Laughter.]

Senator PROXMIRE. In any event I think you are aware of the dilemma the Appropriations Committee now faces. We are under terrific pressure to hold down spending, especially in the nonmilitary area. I think we can make a stronger case for holding down spending in the military area than we can in the nonmilitary area, but spending pressures are a fact of life. So let me ask you this question. In your testimony, you discuss research into family and household structure. At a time when we are facing cutbacks in the testing of vaccines and the attack on genetic diseases, to take two examples, do you think we should continue our current level of support for demographic research at NIH?

Mr. TEITELBAUM. It is a very minor amount of money, Mr. Chairman. It depends on whether you are looking for the biggest payoff, the biggest bang for the buck. The family structure, which is the subject you just referred to, if you look around the United States and ask yourself, what is a principal source of major health problems in the United States, have a look at the rate of families' dissolution, single parent families, adolescent pregnancy, and consider, as the previous witness mentioned, the costs of a single damaged birth to the health care system of the United States, which I think we all agree is principally a curative system.

Senator PROXMIRE. Don't we have that information? Isn't that established?

Mr. TEITELBAUM. I think the answer is we didn't know it. Now we know it. It has been on the front cover of Time magazine. But 15 years ago, to their great credit, I think, NICHD anticipated that there were major changes going on in the family structure and in the propensity of teenagers to bear children and began a basic research program on that subject.

It takes 5 years, as you can appreciate. I know very well. It takes several years to develop basic knowledge and data sources on a subject like that. And when it became an issue of public policy for the first time, and it is not so long ago, really, there was data, there were data there, and the data came, I think, out of the foresight of an institute that has a long-term view and a preventive health view.

I think you have to make decisions, Mr. Chairman, at the margin. I understand that. If you are asking me, do I think at the margin if these moneys are very well spent or moderately well spent, I would say they are very well spent. If you ask me, should they be quadrupled, therefore, or multiplied by 10, I would say no. I don't think they justify a large enormous investment,but a modest or a small investment, such as they are, I think, is fully justified.

Senator PROXMIRE. Thank you very much, Mr. Teitlebaum.

Mr. TEITLEBAUM. Thank you, Mr. Chairman.

STATEMENT OF ALVIN V. BLOCK, PRESIDENT, ELECTROCHEMISTRY-SEPARATIONS-ANALYSIS, BEDFORD, MA

Senator PROXMIRE. I understand that Mr. Block has to testify in the House very promptly. If he is here, we will hear from him right now. Mr. Block is president of the Electrochemistry-Separations-Analysis [ESA] Group in Bedford, MA.

Mr. BLOCK. Mr. Chairman and members of the committee, I am Alvin Block, president of ESA, a biomedical and manufacturing corporation in Bedford, MA. Americans are living longer, and behind that positive phenomenon lies a negative reality: the fact that those extended lifespans are apt to be marred by debilitating diseases.

It is, in fact, the aging of America, that extra stretch of time, which gives prominence to such degenerative diseases as Alzheimer's, Parkinson's, and Huntington's, as well as disorders such as schizophrenia and depression.

Each is a disease which can devastate its victim, his family, and his life's savings. In any given year, as many as 2½ million Americans, victims of Alzheimer's disease, spend $39 billion on care. Huntington's and Parkinson's diseases combined cripple some 500,000 men and women at an estimated cost of $2.5 billion.

Schizophrenia affects 1½ million adults and carries a $30 billion price tag. Major depression afflicts some 5 million adults at a cost which cannot even be calculated. Mr. Chairman, we are talking about billions and billions of dollars.

Tragedy leaks these disorders. Scientists say that the chemical makeup of the brain, more specifically, the configuration of its neurotransmitters, is the key to the understanding of these disorders. These chemicals, the brain's switchboard, transmit messages critical to the control of the body and report on its state of health.

As the body starts to malfunction, it is reflected in changes in the neurochemical patterns of the brain. Based on a new technology, our company, ESA, a pioneer in biomedical research, has developed an instrument to track these chemicals.

Working with medical researchers from the Harvard Medical School, Mass General Hospital and others, we find that biochemical patterns uniquely describe a number of disorders. Researchers have identified an abnormality in the neurotransmitters of Alzheimer's disease; detected the possible manufacture by the body of neurotoxins in Huntington's disease; and discovered neurochemical differences among several forms of severe pain and developed ways of measuring neurochemical patterns in depressions and schizophrenia.

Phase 2 SBIR support from the Division of Research Resources has greatly increased our ability to develop this technology and make it available to the scientific community.

PREPARED STATEMENT

It is critical that this technology be made available to a wide spectrum of key researchers. We ask the committee to ensure that budget cuts will in no way jeopardize this program and its promise of major medical progress. We support the budget recommendation of the delegation for basic biomedical research for additional funding for biomedical research.

Thank you.

[The statement follows:]

STATEMENT OF ALVIN V. BLOCK

Americans are living longer. Behind that positive phenomena lies a negative reality -- those extended life spans are apt to be marred by debilitating diseases.

It is, in fact, the aging of America - that extra stretch of time - which gives prominence to such degenerative diseases as Alzheimer's, Parkinson's and Huntington's, as well as an increase in schizophrenia and depression.

Each is a disease which can devastate its victim, his family, and his life's savings. These disorders not only tear away at the economy, but weaken the fiber of an otherwise rich human resource.

Let's look at the numbers. In any given year:

- As many as 2.5 million Americans -- victims of Alzheimer's disease -- spend 39 billion dollars on care.
- Huntington's and Parkinson's diseases combined cripple some 500,000 men and women at an estimated $2.5 billion.
- Schizophrenia affects 1.5 million adults and carries a $30 billion price tag.
- Major depression afflicts 4.9 million adults which, when combined with alcoholism and drug abuse, robs the economy of $106 billion.

We are talking about hundreds of billions of dollars, yet these figures do not reveal the loss of productivity or quality of life.

These disorders have characteristics in common. Tragedy is one - emotional and financial to the individual and their family. Scientists say there is another common characteristic that lies in the chemical makeup of the brain. This characteristic is in the difference in the patterns of their neurotransmitters from normal.

These chemicals - the brain's switchboard - transmit messages critical to the function of the brain and report on the state of the body. As the body starts to malfunction, it is reflected in the neurochemical patterns of the brain.

In order to detect and to understand the pathology of such diseases, it is necessary to track these chemicals, and to study their patterns, structure and alignment.

Our company, ESA, a pioneer in biomedical research, has designed an instrument to do just that. In 1984, we built an instrument which, in effect, provides a window to the chemistry of the brain.

Our technology enables us to track, measure and evaluate the behavior of neurochemicals. We find it is the pattern of these neurochemicals which forms a profile of various diseases.

Through the measurement of such neurological patterns we may have in essence, discovered the "blueprint" of a disease. Perhaps, given time and further analysis, we will discover distinctions as fine as that of a fingerprint.

We are, however, a long way from that or from treatment and prevention of these diseases. Nevertheless, the body of scientific knowledge is greatly enriched and growing daily.

While the technology must be given broader exposure, this instrument has so far enabled researchers to:

- identify an abnormality in the neurotransmitters of Alzheimer's patients;
- detect the possible manufacture of neurotoxins, by the body, in Huntington's disease;
- discover neurochemical differences among several forms of severe pain;
- develop ways of measuring neurochemical patterns in depression and schizophrenia.

These studies are being conducted with Harvard Medical School, Massachusetts General Hospital, Boston University Medical Center, Bedford and Brockton Veteran's Hospitals, and McLean Hospital, Belmont, Massachusetts and

are now proceeding at a rapid rate -- thanks to the Phase II SBIR support of the Division of Research Resources at NIH.

Such support enables ESA to automate the equipment and to computerize its data processing operation, making it even more effective.

Using ESA equipment, researchers at Ohio's Wright State University School of Medicine, in collaboration with NASA, were able to distinguish between the neurochemical and biochemical differences of motion susceptible and non-susceptible animals and to develop a pharmacological remedy. The remedy prevented motion sickness in two sets of studies. This promises a similar solution to human motion sickness, post-operative nausea, and nausea resulting from chemotherapy.

It is critical that this technology be made available to key researchers. We ask the committee to ensure that budget cuts will in no way jeopardize this program and its promise of major medical progress. A successful conclusion to this development program should result in a significant contribution to the reduction of national health care costs. With continued support, it is possible that we could see a payback as soon as 3-5 years.

Senator PROXMIRE. Thank you very much, and congratulations on the fine work you are doing. There is nothing more heartbreaking, as you have put it so well and as you demonstrate by your statistics, than these diseases affecting so many millions of Americans. Apparently you and your company are doing a superb job in developing answers to these problems.

Mr. BROOK. We feel that technology offers a tremendous opportunity for helping the people who are afflicted and also the potential for reducing the cost of health care.

Senator PROXMIRE.You make a fine case. Thank you very much, sir.

The committee is falling behind schedule here. I understand that Dr. Straatsma has a plane to catch at 12:15. So we are going to put you on, Dr. Straatsma, and then go right to Dr. John Brooks.

STATEMENT OF BRADLEY R. STRAATSMA, M.D., RESEARCH TO PREVENT BLINDNESS, INC. (CALIFORNIA)

Dr. STRAATSMA. Thank you, Senator Proxmire. I am Dr. Bradley Straatsma. I am director of the Jules Stein Eye Institute and professor and chairman of the Department of Ophthamology at UCLA School of Medicine. I am here representing the citizens committee budget for the National Eye Institute in 1987.

Vision is man's most important and highly developed sense. The best possible vision is of critical, precious value to every American. Two separate Gallup polls have shown that vision and the thought of its loss is a great fear among Americans, fear second only to the fear of cancer. We know that by judicious investment, we can help eliminate much of the blindness that is present in this country and fortunately, this committee, over many years of support for the National Eye Institute, has developed a national research program that saves the vision of literally thousands of Americans every year.

The National Eye Institute research program is guided by a national plan. I served as chairman of the first committee to develop a national vision research plan in this country in 1975. The current plan covers the period of 1983 and 1987 and is the product of more than 250 scientists working for a number of months to develop priorities, search for opportunities, and determine the best pathways for investment.

With judicious investment, research in vision and eye disease can be a very cost-effective investment to the American public. Illustrating the effectiveness of vision and research, the diabetic retinopathy study cost approximately $10 million and results in a saving in economic terms of over $450 million per year.

This year, we have the first results from another clinical trial, the early treatment of diabetic retinopathy study [ETDRS]. This trial is conducted at a cost of about $4 million a year but results now in a saving of over $100 million per year for the people of the United States.

These indications of cost-effective research must be considered in conjunction with the overall budget that is requested by the citizens committee. A budget of $245 million is the recommendation we present to you. This represents the consensus of the National Advisory Eye Council; the Association for Research in Vision and Opthamology; Research to Prevent Blindness; the National Retinitis Pigmentosa Foundation; and the American Academy of Opthamology.

The budget provides support in five major categories: retina, cornia, cataract, glaucoma, and vision processing. Retinal disease is probably the largest single category of eye disease affecting our population. At least 750,000 Americans are unable to read newsprint even with the aid of glasses; 200,000 are legally blind as result of this group of disorders. For the premature infants of low birth weight, one of the major causes of retinal disease is attacked with a multicenter clinical trail to try to determine the efficacy of cryotherapy in preventing retinal detachment and blindness. For the diabetics, probably 10 or 11 million people in this country, we have the sorbinil retinopathy trial underway, and the therapy oriented ETDRS's and diabetic retinopathy vitrectomy study. These investigations are among those that are working to solve the problems of retinal disease in a practical sense.

Corneal disease affects some 3.7 million people in this country each year, and from that, assumes an expenditure of about one-third of every dollar that is spent on eye care in the United States. The major cause of this disorder is herpes simplex virus infection of the cornea. Scientists now recognize the problem. There is a recurrence that affects about 1 out of every 4 patients who has herpes simplex corneal disease. Scientists have now developed an in vivo model to study this.

Another disorder affecting the corneal and external eye is concerned with the acquired immune deficiency syndrome, AIDS. These patients may develop and extra problem such as Kaposi's sarcoma, as well as diseases affecting the retina and retinal inflammation.

Cataract is another major problem. With the steadily increasing incidence among Americans greater than 50 years of age, for example, between 52 and 64 years of age, among 5 percent of Americans have cataracts, responsible for a decrease of vision to 20/30 or less. But by age 75 to 85, that figure that increased to some 46 percent of Americans with that degree of cataract.

Indicating the extent of the problem, nearly 1 million people have had cataract surgery in the United States in 1985. Most of these had an intraocular implant, and nearly 90 percent of these people recover visual acuity of 20/40 or better, sufficient for them to function well in our mechanized information transfer society.

At present, we need more research in cataract to understand its causes to try to prevent and retard its progression. Some of that work started under the National Eye Institute with sorbinal studies and certainly deserves our high priority and continuation.

Glaucoma affects more than 1 million Americans, some 60,000 of whom are blind. Studies there should be directed to greater education of patients concerning use of medications and the development of new medications that can be used once or twice a day rather than requiring repeated installations.

Strabismis causes some 80,000 Americans to have eye muscle surgery every year. This needs to be studied further, and for young patients with strabismis, we now have a trial.

Senator PROXMIRE. Doctor, can you wind up in another minute?

Dr. STRAATSMA. Let me summarize and say that we are concerned about a number of things affecting vision. We recognize it takes an integrated plan to achieve the results that we really think are important for the American people. The National Eye Institute has such a plan. The citizens committee feels that by supporting the amount of some $245 million for this coming year we can support the categorical areas that I described; we can provide for training; we can provide for the excellent intramural program, and we can go on and support some facilities that are desperately needed for the eye research community.

Thank you for this opportunity to share this.

Senator PROXMIRE. Thank you very much for a fine presentation. You are certainly speaking of a need that all of us recognize as vitally important. You are requesting a one-third increase in grant funding. Can you tell us what percentage of approved eye research would be funded under your budget as compared with the percentage currently funded?

Dr. STRAATSMA. The National Eye Institute has placed great priority on the individual research grants. Thus, they have had a higher percentage of funding than many other institutes by choice, not by chance.

We have deliberately tried to keep that as a high element. If the President's budget for 1987 is approved as presented, the funding rate will be about 37 percent. If citizens committee's is approved as presented, it would be about 56 percent.

Senator PROXMIRE. What is the present percentage?

Dr. STRAATSMA. A little below 50 percent.

PREPARED STATEMENTS

Senator PROXMIRE. Thank you very much. This is a high priority. I hope you make your plane. If it is flying from National Airport, you have got a fighting chance. If it is flying from Dulles, forget it.

Dr. STRAATSMA. Thank you. I was pleased to be able to present this testimony.

Senator PROXMIRE. Thank you very much. Your statement will be included in the record at this point along with other statements submitted for the record on appropriations for the National Eye Institute.

[The statements follow:]

STATEMENT OF BRADLEY R. STRAATSMA

I am Dr. Bradley Straatsma, Director of the Jules Stein Eye Institute and Professor and Chairman of the Department of Ophthalmology at UCLA School of Medicine in Los Angeles. It is my privilege to present the Citizens' Committee Budget for Fiscal Year 1987 under the auspices of Research to Prevent Blindness (RPB), the world's leading voluntary organization in support of vision research.

Vision is man's most highly developed sense. Sight is important for learning, using tools and devices, moving about, and enjoying human endeavor. For all Americans, best possible eyesight is precious.

Conversely, two separate Gallup surveys conducted a decade apart indicate that the fear of blindness among Americans is second only to fear of cancer. Fears are warranted, because more than 11 million Americans have significant visual impairment, 1.4 million of these have severe loss of vision, and more than half a million Americans are legally blind. The cost of visual impairment and blindness can be measured in terms of human suffering and in a cost to the American people of more than $14 billion a year.

Recognizing the importance of vision as a national health issue, Congress took a monumental step when it established the National Eye Institute in 1968 with instructions to develop and lead the nation's vision research program. Since then, the far-sighted actions of Congress and this Committee have provided the organizational base and financial support for a national research effort that saves eyesight for thousands of Americans each year and is poised on the brink of major, predictable, and cost-effective achievements.

The National Eye Institute has been guided by a series of carefully constructed national Vision Research Plans. I served as Chairman of the Committee that produced the first national Vision Research Plan in 1975 and appreciate the value of research planning in identifying needs and opportunities, establishing priorities, and guiding support. As a consequence, the National Eye Institute and the nation's research community act in concert as a coordinated team.

The current national Vision Research Plan: 1983 - 1987 stemmed from the participation of more than 250 leaders of ophthalmology and visual science in the

United States and around the world. The national plan has documented areas in which research has been effective and blinding diseases have been reduced or stopped. Even more important, the national plan has identified areas of current need which can now be approached with existing technology and available scientific manpower. This plan presents the realistic opportunities for scientific advance. With judicious investment, we can reduce the tragedy of blindness and cost-effectively reduce the burden of health care for the people of the United States.

Illustrating cost-effective research, the nationwide Diabetic Retinopathy Study (DRS) established laser photocoagulation as a treatment that reduces by 60% the blindness from proliferative diabetic retinopathy. The DRS cost $10.5 million; the estimated savings, in economic terms, are $454 million per year. Now, in 1986, we can add to this the first reported results of the Early Treatment Diabetic Retinopathy Study (ETDRS). This multicenter clinical trial documented that focal laser treatment can halt or even reverse the sight-impairing macular edema that is often associated with less advanced stages of diabetic retinopathy. The cost of the ongoing ETDRS is $4 million and the savings from this research are calculated at nearly $100 million each year. The laser, an epochal scientific advance, is widely used in communications and industry, but according to its discoverer, Dr. Theodore Maiman, the first practical application of laser technology was the treatment of retinal disease. With prudent investment, we continue to achieve major benefits from laser treatments of the retina and several other parts of the eye.

For Fiscal Year 1987, the Citizens' Committee Budget recommends $245 million to sustain the multifaceted, carefully planned program of eye and visual system research. This Budget represents the consensus of the National Advisory Eye Council and the considered judgment of Research to Prevent Blindness, the Association for Research in Vision and Ophthalmology, and the American Academy of Ophthalmology. It is not an inflated figure but a realistic statement of the resources required to maintain the nation's eminently successful program to preserve the best possible eyesight for Americans.

Further considering this Budget, research supported by the National Eye Institute is categorized in five program areas: retina, cornea, cataract, glaucoma, and strabismus-visual processing.

Retinal diseases prevent over 750,000 Americans from reading ordinary newsprint even with the aid of eyeglasses and are responsible for legal blindness of 200,000 citizens. In newborn infants with low birth weight, the retinopathy of prematurity is being attacked with a multicenter clinical trial to determine the efficacy of cryotherapy in preventing retinal detachment and blindness. For the 10 to 11 million diabetics in this country, diabetic retinal disease is being systematically studied by the prevention-oriented Sorbinil Retinopathy Trial and the therapy-oriented ETDRS and Diabetic Retinopathy Vitrectomy Study. The Sorbinil Retinopathy Trial, culminating nearly a decade of research at the National Eye Institute, is designed to determine whether drugs that inhibit the enzyme aldose reductase can prevent or retard diabetes-associated eye disease and neuropathy.

For the approximately 80,000 Americans with retinitis pigmentosa (RP) and the several hundred thousand people who are in their families or carry the RP genes, there is no effective treatment, and basic science research is needed. In the past year, neurobiological studies of visual cells (photoreceptors) in the retina have elucidated critical steps in the transduction process. This is the critical "firing stage" that occurs between absorption of light by the visual pigments and the generation of an impulse that is transmitted from the visual cell to the next cell in the hierarchy of the visual system. Transduction research is likely to increase our understanding of retinitis pigmentosa and our fundamental concepts of the central nervous system.

Corneal disease or injury affects approximately 3.7 million Americans each year. Often painful as well as sight-impairing, corneal and external eye disease accounts for one third of every dollar spent on eye care in this country. Herpes simplex virus (HSV) infection is the leading cause of corneal blindness. The initial infection usually subsides after treatment, but nearly 25% of those afflicted experience a recurrence or a complication within two years. Research scientists have developed an in vivo experimental system that enables study of the process that permits a latent HSV to become a reactivated infection. This is a major advance in efforts to decrease or prevent recurrent HSV infection of the eye.

The external eye may also be affected in patients with acquired immunodeficiency syndrome (AIDS). Caused by the retrovirus HTLV-III, which is present in an estimated one to 1.5 million Americans, AIDS has been diagnosed in approximately 18,000 Americans to date. AIDS patients may develop Kaposi's sarcoma on the external eye, cotton wool patches in the retina, or sight-destroying chorioretinal inflammation. Basic research on AIDS and therapeutic drug trials to control the chorioretinal inflammation are needed.

Cataract may be present at birth or develop at any age but is increasingly frequent among Americans greater than 50 years of age. For example, cataract causing decrease of vision to 20/30 or less is present in 5% of Americans between 52 and 64 years of age, in 18% of Americans between 65 and 74 years of age, and in 46% between 75 and 85 years of age. Evidencing the extent of cataract-related vision impairment, in 1985 about one million Americans had cataract surgery, usually with an intraocular lens implant, which restored visual acuity to 20/40 or better in nearly 90% of the patients. Moreover, cataract surgery was increasingly performed as an outpatient procedure in the United States with an estimated savings of $500 million each year. Skilled microsurgery, implant quality control, and neodymium-YAG laser technology are among factors that have made cataract surgery increasingly safe and cost-effective for Americans. Cataract research is needed to prevent and retard the progression of lens opacities. Among current studies, investigations supported by NEI are using molecular biology-DNA probes to establish chromosome abnormalities in dominant inherited congenital cataract and precise biochemical analyses to study lens protein changes associated with aging-related cataract. A prominent factor in at least some cases of aging-related cataract appears to be oxidation damage caused by ultraviolet and near-ultraviolet light.

Glaucoma, referring to diseases in which increased pressure in the eye is destructive to vision, is present in 1.2 million Americans, many of whom have a decreased visual field and more than 60,000 of whom are legally blind. Most glaucoma patients can control the disease with self-administered eye drops several times daily. Recent research has shown, however, that a significant percentage of patients do not use the prescribed medication regularly. This emphasizes the need for patient education to enhance compliance.

For glaucoma patients, research has documented the efficacy of new medications that require instillation only one or two times daily and the value of argon laser trabeculoplasty, a procedure that increases aqueous humor outflow. For

Fiscal Year 1987 glaucoma research includes studies of aqueous humor formation, epidemiologic risk factors, and topical carbonic anhydrous inhibitors.

Strabismus, amblyopia, and visual processing account for significant disease in a large number of Americans and cause 80,000 people to undergo eye muscle surgery each year. Research supported by NEI has delineated the physiological basis for amblyopia ("lazy eye syndrome") and the "critical period" within which congenital cataract surgery must be carried out to be visually successful.

For strabismus (misaligned eyes) a multicenter clinical trial of presurgical prism adaptation is in progress in an effort to increase the successful outcome of eye muscle surgery. Eye muscle surgery with adjustable sutures is utilized with increasing frequency, and small injections of botulinum A toxin are used to produce specific and often time-limited effects. In Fiscal Year 1987 and thereafter, neurobiological research on neurotransmitters and the molecular development and structure of the oculomotor system are needed.

Although NEI-supported research is categorized in five major program areas, vision stems from the eyes and brain, functioning as an integrated system of awesome complexity. The image focused on the retina is sensed by over a hundred million visual cells (photoreceptors) in each eye, processed in the retina, and transmitted through more than a million fibers in each optic nerve to the centers of vision in the brain. Each second the eyes and brain perform about a hundred billion "floating point logical operations" to change the two-dimensional image formed on the retina of each eye into symbols that encapsulate the solid reality of the original object. For this intricate system, research has documented that early detection and prompt, effective treatment of common vision-threatening eye diseases will preserve sight and prevent blindness for many Americans.

The 1987 Citizens' Budget provides support for the five vision research program areas, for research training, and for the outstanding intramural research program of the NEI. It also addresses the critical need for adequate physical space to support the growing capabilities of vision scientists. Many of our universities and vision research institutes have long since outgrown their limited and often antiquated quarters. Eight years ago Research to Prevent Blindness (RPB) determined that the national need for eye research renovation and construction funds was more than $70 million, an amount hardly comparable to today's costs. The private sector has done its part in generously supporting the construction of eye research centers throughout the country, and the response of the Congress over the past two years has been most welcome and encouraging. However, greater Federal assistance is essential to the growing research effort. The Citizen's Budget therefore includes an urgent request for $10 million for Extramural Laboratory Renovation and Construction -- an expenditure that will be cost-effective in economic terms and in the saving of human sight.

In summary, best attainable vision is precious for every American. Research has shown that early diagnosis and effective treatment of eye disease saves vision each year for thousands of Americans who would otherwise be blind, and research is the only hope for Americans afflicted with diseases for which there is no effective treatment at this time. With commendable initiative, NEI is guided by a detailed and realistic national Vision Research Plan that identifies research needs and opportunities, establishes priorities, and promotes cost-effective research. Vision research is important to all Americans and increasingly important to the growing number of elderly Americans who are at risk for aging-related eye disease. I earnestly request that this Committee recommend approval of the Citizens' Budget of $245 million for the National Eye Institute for Fiscal Year 1987. Proposed expenditures in each of the categories of eye disease are specified in the Financial Tables appended to my statement.

I deeply appreciate the opportunity to present this testimony and would be pleased to respond to any questions. Thank you.

NATIONAL EYE INSTITUTE
CITIZENS' BUDGET

(Dollars in Thousands)

	Fiscal 1986 Appropriation	FY 1986 President's Revised Request	Fiscal Year 1987 President's Budget Request	Fiscal Year 1987 Citizens' Budget
BY ACTIVITY:				
Grants:				
Research Grants....	$151,793	$140,045	$139,037	$185,373
Extramural research laboratory renovation, construction and instrumentation....	3,300	3,158	0	10,000
Core and center grants.............	6,100	5,838	5,400	8,700
Individual training...........	2,615	2,503	2,388	3,500
Institutional training...........	2,616	2,504	2,388	3,500
Total Grants.......	166,424	154,048	149,213	211,073
Direct Operations:				
Intramural laboratory and clinical research..	14,901	14,210	15,523	16,127
Research and development contracts..........	6,649	6,363	7,215	10,000
Biometry epidemiology and field program......	1,150	1,150	1,200	1,500
Research management and program services...........	5,948	5,591	6,050	6,300
Total Direct Operations.........	28,648	27,314	29,988	33,927
Total NEI Obligations........	195,072	181,362	179,201	245,000

(Dollars in Thousands)

	Fiscal 1986 Appropriation	FY 1986 President's Revised Request	Fiscal Year 1987 President's Budget Request	Fiscal Year 1987 Citizens' Budget
BY PROGRAM:				
Extramural Research:				
Retinal and Choroidal..........	$77,300	$71,228	$70,689	$95,605
Corneal Diseases...	28,200	26,253	26,149	35,238
Cataract...........	14,254	13,311	13,275	17,867
Glaucoma...........	15,830	14,731	14,684	19,773
Strabismus, Amblyopia, and Visual Processing..	34,189	31,730	31,631	42,590
Extramural Laboratory Renovation, Instrumentation and Construction....	3,300	3,158	0	10,000
Total Extramural Research...........	173,073	160,411	156,428	221,073
Intramural Research:				
Laboratory and Clinical Research, Biometry and Epidemiology.......	16,051	15,360	16,723	17,627
Research Management and Program Services	5,948	5,591	6,050	6,300
Total Intramural...	21,999	20,951	22,773	23,927
Total NEI Obligations	195,072	181,362	179,201	245,000

STATEMENT OF THE ASSOCIATION FOR RESEARCH IN VISION AND OPHTHALMOLOGY, INC.

The Association for Research in Vision and Ophthalmology (ARVO) strongly supports the proposed 1987 Citizens Budget of $245,000,000 for the National Eye Institute (NEI) of the National Institutes of Health (NIH).

Founded in 1928 to encourage and assist research, training, publication and dissemination of knowledge in vision and ophthalmology, ARVO has over 4,000 members representing every region in the United States. The majority of its membership conducts serious vision and ophthalmology research supported by NEI. This research has resulted in dramatic improvements in the treatment of more than eleven million Americans suffering from permanent visual disabilities. Examples of recent significant accomplishments due to funding sponsored by NEI include:

- The development of a focal treatment with a laser that can halt or even reverse the visual loss that occurs in many people with diabetic macular edema.
- The location of the gene believed responsible for retinitis pigmentosa, a blinding hereditary disease that strikes children and adolescents. This information may ultimately lead to the development of gene therapy for this disease.
- A decade of basic research on the formation of diabetic cataracts through the action of aldose reductase has not only paved the way for the development of drugs such as sorbinil, that inhibit the enzyme, but has also opened other avenues of investigation into the role of aldose reductase in a variety of diabetic complications. Ongoing work should lead to a more precise understanding and control of the pathological effects observed in diabetes and be useful in designing anti-cataract drugs.

The proposed 1987 Citizens Budget for NEI also recognizes the ongoing need for support in the training of vision and ophthalmology researchers. The current advancements in the diagnosis and treatment of eye diseases must be continued. In addition, the budget includes funding for the modernization of research facilities. This is particularly critical in light of the newly revised Public Health Service Animal Welfare Policy, which places more stringent regulations on the care of laboratory animals.

The ARVO membership believes the proposed $245,000,000 for NEI is both necessary and justified, if the level and quality of eye research is to continue in this country. We urge the committee members to review the significant accomplishments of the NEI and consider the porposed 1987 Citizens' Budget as essential to the treatment of the visually impaired citizens of this country.

Statement of the National Retinitis Pigmentosa Foundation

We of the National Retinitis Pigmentosa Foundation are in complete support of the 1987 Citizens Budget Request of $245,000,000 for the National Eye Institute of the National Institutes of Health. This Citizens Budget would allow each research program activity, through which vision research is pursued, to continue in 1987 with strength and stability. In contrast, the 1987 President's Budget Request for the National Eye Institute is lower than the estimated 1986 budget and would result in lost momentum and constricted efforts in vision research.

The momentum generated by recent exciting research in the field of eye disease is too valuable to be sacrificed by an inadequate budget. The National Retinitis Pigmentosa Foundation (NRPF) represents 400,000 Americans who suffer severe loss of vision, even blindness, from retinal degeneration. Retinitis pigmentosa, macular degeneration and Usher's syndrome are the most frequent forms of blinding retinal degeneration. At this time there is no prevention, treatment or cure. People affected by these diseases depend upon our nation's research programs to give them hope that the causes of blindness will eventually be understood. They anticipate and scrutinize each step researchers make toward finding the cure to the eye disease from which they, and possibly their families, suffer greatly.

In the belief that medical research will always be a top national priority, this large group of vision impaired people are making their own unique and precious contributions: their eyes, their histories, and their blood. Under three programs designed, supported and vigorously administered by the NRPF,their contributions are made available to researchers. But these contributions would be underutilized or even lost if sufficient research funds were not available for the relevant studies.

One of these programs, the National Retina Donor Program, was initiated by NRPF in 1980 to meet the acute, increasing need of researchers to study retinal tissue from deceased persons affected by retinal degenerations or from members of their families. A very reliable retina donor notification and retrieval system has been developed so that eyes can be prepared and shipped to researchers as soon as possible after death to maximize the specimen's usefulness in biochemical research. These invaluable anatomical gifts have greatly enhanced research efforts.

A computerized registry program of family histories has been developed by the NRPF and is constantly being updated in an effort to register all persons with an inherited retinal degenerative disease. From this registry, researchers are able to identify and contact the members regarding participation in relevant research programs and clinical treatment trials. Since large numbers of volunteers are needed for most studies, the registry is a valuable resource for investigators. It should not go unused due to insufficient research funds.

Three multi-generational families totaling 350 members, with inherited retinal degeneration, have volunteered to donate blood samples for a program sponsored by the NRPF. Under this program, blood cell cultures will be established and banked to provide to researchers an unlimited biological resource for studies on the genetics of retinal degeneration. DNA can be isolated from the cultured cells and used to identify and characterize, through recombinant DNA approaches, the various genes causing retinal degeneration. Although such investigations are expensive, they provide insights into disease at the most basic, molecular level. These cell cultures will be used only if research funding is available for such studies.

Recent research break-throughs and the current development of research resources constitute the momentum upon which new findings are built. If this momentum is interrupted due to inadequate funding of research by the National Eye Institute, our future progress will be seriously jeopardized.

We urge that you give your full and enthusiastic support to the 1987 Citizens Budget for the National Eye Institute so that important programs, exemplified by those described above, can be used for vision research. The hope of the vision impaired lies in this research, to which they eagerly and willingly make their own special contributions. We also urge that you support provision of funds for instrumentation and construction at the level of $10 million as requested in the Citizens Budget. Even though adequate equipment and facilities are a basic requirement for conducting research, the President's budget request has completely neglected this need.

STATEMENT OF JOHN G. BROOKS, M.D., TRUSTEE, NATIONAL SUDDEN INFANT DEATH SYNDROME FOUNDATION

Senator PROXMIRE. Our next witness is Dr. John Brooks, M.D., trustee, National Sudden Infant Death Syndrome Foundation. Dr. Brooks?

Dr. BROOKS. Mr. Chairman, thank you for the opportunity to speak to you today. I am a pediatrician specializing in breathing problems of children. I am the director of pediatric pulmonary medicine at the University of Rochester in New York. I am coming before you today as a trustee of the National Sudden Infant Death Syndrome Foundation to explain and emphasize the importance of adequate funding through NICHD and the Division of Maternal and Child Health for research and services related to sudden infant death syndrome, or SIDS, as I will call it. My remarks today will be general, but I have prepared a more detailed statement which I have submitted for inclusion in the record.

Senator PROXMIRE. It will be printed in full in the record.

Dr. BROOKS. Thank you. As Senator Weicker knows through his long involvement with the National SIDS Foundation and unfortunately, as some of your legislative colleagues specifically Senator Hollings, Congressman Garcia and Lujan know through painful personal losses within their family to SIDS, SIDS is a ruthless and an indiscriminate killer of babies which strikes without warning and really spares no segment of society, no race, no social class.

In the United States each year, over 7,000 babies die from this devastating problem, making it the leading cause of death between 1 week of age and 1 year of age.

So in addition to being a deep personal tragedy for each affected family, SIDS is really a major contributor to the unacceptably high infant mortality which we have heard about earlier in this hearing, and therefore, is a major public health concern for this country.

In order to succeed in our national goal of lowering infant mortality, we must aggressively attack the problem of SIDS. In addition to its impact on the individual families who suffer losses, SIDS, in a very real way, affects almost all parents and grandparents of young infants as they realize that they, too, are vulnerable to a SIDS loss, and so they worry. How many of us seated in this room have walked in to our children's room time and time again just to make sure that the child is still breathing, because we have heard about SIDS and worry about it?

So when the tragedy of SIDS is finally eliminated, it will positively benefit millions of Americans. What can we, what must we do now to control SIDS, and how can you and your committee help in this endeavor?

I think that the primary answer is to support high quality, promising research, and there is a lot of such high quality research, a lot of avenues to pursue. Much has been learned through past research, but SIDS is still largely unpredictable and largely unpreventable. As a result of much of this past research, there are many important new avenues and new hypotheses which we must pursue.

We also now have available to us new technologies which provide many previously unavailable opportunities, and we must attack, start with these opportunities and follow up. But these opportunities are costly. These research projects are costly.

For example, one ongoing study investigating the possible role of the brain stem in regulation of cardiorespiratory control will cost over $800,000, and this is close to the entire amount currently budgeted for SIDS research for fiscal year 1987. This clearly is not enough. So it is imperative that the $1.1 million which is currently earmarked for 1987 for SIDS specific research be expanded to $35 million, and this would only return us to the 1979 level.

Finally, we must also support services for bereaved families, support education, and national data collection so we can know what progress we are making by re-establishing a mandate for block grant funding of State SIDS projects. These are described at greater length in the material which has been circulated.

In conclusion, to me as a physician, a SIDS death is really antithetical, the ending of my practice of medicine before I can begin. In the private sector, parents, other family members, scientists, and many volunteers are working tirelessly on the SIDS problem. I am hopeful that with your efforts to establish sound public policies and adequate funding for the SIDS efforts that we can work together, the public and the private sector, to eliminate SIDS and, therefore, take a giant step toward the high Federal priority of decreasing infant mortality.

Thank you, and I would be happy to address any questions.

Senator PROXMIRE. Thank you, Dr. Brooks. I have one question. Do we have any idea of how the death rate from sudden infant death syndrome in this country compares with the death rate from SIDS in other countries?

Dr. BROOKS. We know there are some countries, for example, Scandanavian countries where it is lower. In England, it is about the same as it is here. In many of the underdeveloped countries, it is not known, because there isn't adequate data collection, and it requires autopsies to make a diagnosis.

Senator PROXMIRE. Do you have any idea why it is lower in Scandanavian countries?

Dr. BROOKS. It has been attributed to better prenatal care, which ties in nicely with the discussions about infant mortality, because most things that are assorted with decreased infant mortality in general, at least at a national level, are associated with lower incidence of SIDS.

PREPARED STATEMENTS

Senator PROXMIRE. Thank you very much for a fascinating and very helpful presentation.

Dr. BROOKS. Thank you.

Senator PROXMIRE. Your statement will be included in the record at this point along with other statements on appropriations for the National Institutes of Child Health and Human Development.

[The statements follow:]

STATEMENT OF JOHN G. BROOKS

FUNDING AND POLICY RECOMMENDATIONS FOR FISCAL YEAR 1987
SUDDEN INFANT DEATH SYNDROME RESEARCH AND SERVICES

A. National Institutes of Child Health and Human Development (NICHD): $377 Million. This is essentially a "stay even" request to allow promising research which addresses critical needs in infant mortality. When breakthroughs are on the horizon, fiscal cutbacks must be averted.

B. NICHD: Pregnancy and Perinatology Branch -- SIDS-Specific Research: $5 Million. This level of funding would allow the NICHD to fund the Meritorious Research Grant application received in response to a broad-based Request For Applications. To support broad spectrum of vital SIDS research efforts.

C. NICHD: Pregnancy and Perinatology Branch -- Total SIDS-Related Research: $23 Million. To continue support of the substantial research efforts being conducted in areas of high risk pregnancy and high risk infancy (includes the requested increase in SIDS-Specific research dollars).

D. MCH: Federal Mandate of MCH Block Grant Funding of State SIDS Programs:

1. To allow restoration, maintenance and/or continuation of SIDS services and education programs in each state.

2. To ensure uniform reporting of SIDS statistics, vital to evaluating all research and program efforts.

3. To maintain the SIDS Clearinghouse, for distribution of informational and educational materials.

In December of 1984, an infant boy was placed in his crib for a nap. His young parents were secure with their new baby. Their lives had taken on a new joy with their first son. An hour later, when he was to be awakened, he was dead.

These young people had never before experienced death in their lives. They now suffered the harshest kind of grief reaction -- blaming themselves, feeling guilty, not wanting to face this tragedy. These parents experienced grief similar to thousands of parents all over this country: where minor omissions become magnified; where each parent has so many "if onlies" -- if only I had walked into the room sooner, if only I had been more observant, if only...

The baby - Alex - was Congressman and Mrs. Robert Garcia's first grandchild. He died of Sudden Infant Death Syndrome -- SIDS.

In 1986, the United States international ranking in infant mortality is an alarming 15th place. SIDS is the leading cause of death in infants between 1 week and 1 year of age and second only to accidents as the cause of death of children up to the age of 15. During this year more infants will die of SIDS than will succumb to cystic fibrosis, childhood cancer, childhood heart diseasd, and child abuse combined.

Today with increased public awareness of SIDS, or Crib Death, many parents, many grandparents fear this tragedy which claims the lives of over 7,000 infants per year in this country alone. The estimated worldwide figure of SIDS cases in 1985 is 257,000. This serious public health problem has to be the concern of everyone, for SIDS does not respect race, income level, or age of parent. It can happen to any one. Among your colleagues, it has happened to the Garcias. Senator Ernest Hollings lost a grandchild to SIDS; Congressman Manuel Lujan - a child - and there are others. The death of an infant is truly a community event, impacting not only the immediate family, but also relatives, friends, neighbors, colleagues, involved professional (such as clergy, police, physicians, funeral directors, emergency medical technicians) and the list goes on.

When the tragedy of SIDS is finally eliminated, it will positively benefit millions of Americans.

As you may know, SIDS has plagued the human race since biblical times but not until this mid-century has serious medical attention been focused on its causes and concerns. It was not until 1974 that the government became involved through the Federal SIDS Act, but in spite of efforts of the private and public sector, the statistics have not changed.

However, key research in the last decade has increased our knowledge about SIDS and points to important avenues for further study. For instance, we now know that SIDS babies are subtly different from normal even from before birth. They develop more slowly in utaro and continue to develop and grow more slowly after birth, their hearts beat faster, their breathing is faster, and they are ill more often than matched control infants. These differences are so subtle that even the most astute physician cannot yet identify the potential victim. This is one avenue that demands our increased attention. We are closer than ever before to achieving this capability. Only with continued research can scientists develop the means to diagnose susceptible infants and move towards preventing SIDS.

We now know that the welfare of mothers is critical in diminishing the risk of SIDS. Teenage mothers are more vulnerable than women in their 20's and 30's and smoking mothers are at substantially increased risk. Low birth weight babies are at significantly increased risk of SIDS. The need for programs of prevention based upon improvement of maternal well being is paramount.

We now know that the brainstems of some SIDS victims are slightly scarred. The brainstem is the seat of control for breathing and heart action, and it is extremely important to determine whether this "scarring" represents a cause or effect of SIDS. A new Request For Grant Application on SIDS from the National Institutes of Child Health and Human Development (NICHD) encourages investigators to focus efforts on neural control of cardio-respiratory function, particularly at the brainstem level. This is a vitally important line of inquiry.

We now know that there is a small overlap between unexplained prolonged infantile apnea (episodes of not breathing) and SIDS. Major research is underway to explore this relationship.

What do we know in summary? Experts in the field agree that there is likely more than one cause of SIDS. It is reasonable to consider that SIDS may result from a failure not just of one organ system or another, but from a failure of the complex interplay of the regulatory systems required to maintain life. The developing brain with its specific centers is the area where control of life sustaining functions takes place. It is imperative to provide research dollars for a number of promising hypotheses -- to fund more than a single avenue of research in order to maximize our chances of successful outcomes. This is a critical time. Because of today's new, highly sophisticated technology, we can now anticipate research efforts that we could not even dream of a few short years ago. As just one example, researchers can now study not only newborn infants but also the developing fetus, and can evaluate brain function, heart rate and breathing patterns in normal and at-risk fetuses and infants. It is expensive research; it is long term; but it is essential. We must not lose momentum at this strategic time.

In FY 1985, $1.133 million was allocated for SIDS-specific research at NICHD. The budget for SIDS specific research in 1986 is $1.1 million, after recision. The President's Budget for FY, 1987, earmarks $1.1 million for SIDS-specific research. A single project in the area of brainstem research easily costs over $800,000 (close to this entire budgeted amount). The NICHD Request for Applications has stimulated the preparation of numerous, varied and exciting proposals. The money must be made available to allow funding of the best of these.

Research money for primary SIDS studies has not kept pace with the demands and opportunities in this field. Even considering today's trends, SIDS Research has taken a disproportionate share of the cuts. Although the 1985, 1986, and 1987 budgets show a slight increase over the appallingly small amount of $657,000 earmarked in FY 1984, we have a long way to go to even catch up with funding levels of the late 1970's and early 80's. It is imperative that the $1.1 million earmarked for 1987 be expanded to $5 million (which would bring us back to the 1979 level) to allow optimal and expanded research efforts in this vital area.

Until SIDS is eradicated, affected families remain its victims; needy of information, counseling and comfort. The private sector has responded well with its support system built primarily upon those very persons who most intensely feel the need for support. But the fact is that they are incapable of filling the gap created by the curtailment of programs due to Federal budget cuts in the 80's. Just as NICHD is responsible for funding basic research, MCH handles clinical research and sees that research findings are applied to programs at the state level.

You know that direct grants to states ended in FY 1982 and the formerly Federally mandated State SIDS projects no longer exist. The capabilities of those projects across this nation are now extremely varied, from those that competently serve their community to those that have been cut out completely, with the majority struggling somewhere in between. All of them deal with the frustration of uncertain funding and the threat of termination.

Enough programs and research have taken place in the last decade to document the toll of blame and guilt and the complexity of responses of the wider community which SIDS affects. It is paradoxical that in 1986 a Federal Publication on SIDS will be issued detailing the complexity of responses from these very same groups which now are beginning to feel the shock waves of lack of services. Sadly, while infant mortality is the focus of MCH funding for 1986, a major segment, SIDS, has its public services eroded, weakened or terminated.

For example: Hawaii's former $50,000 budget was changed to $20,000. However, last September 30th, the state listed SIDS as "low priority" and all state funding for the SIDS Program was dropped. Montana receives no funding from MCH sources, has no state SIDS Program and only a National SIDS Foundation chapter in Billings to serve the entire state. The state has no allowance for autopsies (the only way to identify a SIDS case accurately) and as recently as last fall, a couple whose child died of SIDS, was initially charged with murder and exonerated only after a full investigation. Without a state program, large geographical states with sparse populations, such as Montana and also Wyoming and Idaho, literally have no ongoing education for public health departments. Alaska's last major educational effort for their widespread health districts was a 1980 teleconference.

There is no NSIDSF Chapter in the state of Idaho; no funds for the seven health districts and no legislation for SIDS autopsies.

Washington State has a catch 22 where Children's Orthopedic Hospital, the site of the SIDS Project, is the Block Grant recipient and hospital personnel needs supercede the Project needs, causing a continual reorganization because of lack of assured continuity. Although there were 181 SIDS deaths in 1984, the 24 hour phone service for families was discontinued in an effort to live within the hospital budget.

Texas has federal projects only in Houston and Dallas which receive $20,000 and $50,000 respectively. While there is state money for autopsies, a Justice of the Peace may request an autopsy but is under no obligation to do so. The State Health Department provides information to the public and professionals "as requested." For example, from the instructor of nursing education in San Antonio comes the information that "only lip service is paid" to educating parents about the importance of autopsies as their metropolitan health district has little formal SIDS management service. According to state statistics in 1984, only 78% of reported SIDS deaths were autopsied. Based on the 2.0 SIDS per 1,000 live births, Texas would have had an estimated 598 SIDS cases but only 351 were reported. The ignorance that a large percentage of SIDS deaths are unproven murders persists among a number of medical personnel.

The Utah Project no longer has the social workers and nurse, leaving only one professional to administer the program. Their small remaining budget which cut back on travel, counseling and educational services was further diminished by the requirement that they transfer to the Medical Department $125 per SIDS death whenever a coroner performs an autopsy.

Florida, once an outstanding Project, now only has resources to gather statistics. Louisiana, with its project in New Orleans is so minimal it is only a "central register" for the SIDS deaths in that state.

New Mexico will face a cutback in budget between 6 and 10% and will be further impacted by state cuts in the Office of the Medical Investigator out of which office they operate.

And so the accounting of cutbacks is tallied. We are currently left without any guarantee that states will continue SIDS-related services. Consonant with the Federal priority of reducing Infant Mortality, I would hope that you see the possibility of Federally mandated MCH Block Grant Funding of State SIDS Programs. Furthermore, because of Confidentiality Legislation in many States, doors do remain closed to programs in the private sector. Without a comprehensive Federal program, there can be no uniform reporting of statistics.

To me, as a physician, a SIDS death is antithetical. The ending of my practice of medicine before I can begin. To a parent it is the theft of joy, hope and the future. And yet we ask so much of those in our organization. We want them to be counseled and to counsel. We want them to be intelligent about their issues, sensitive and helpful managers. We count on them to recruit and use volunteers, to educate the community, to deal with the media and raise money for their cause. Surely it is not asking too much that from you we can win sound public policies and count on you to be partners in this endeavor.

NICHD APPROPRIATIONS FOR SIDS-SPECIFIC AND SIDS-RELATED RESEARCH

(MILLIONS)

	1979	1984	1985	1986	Sequestration 1986	Recision 1986	1987 President's Budget	NSIDSF Recommendation FY 1987
SIDS Specific......	$4.9	$.657	$1.133	$1.300	$1.150	$1.100	$1.100	$5.0
SIDS Related.......	6.2	16.527	17.911	18.300	17.750	17.700	17.800	18.0
TOTAL..............	$11.1	$17.184	$19.044	$19.600	$18.900	$18.800	$18.900	$23.0

STATEMENT OF THE ASSOCIATION FOR CHILDREN AND ADULTS WITH LEARNING DISABILITIES

Mr. Chairman, I am Audrey R. McMahon of the Association for Children and Adults with Learning Disabilities (ACLD). ACLD is a parent-run, voluntary organization with Affiliates in all the States and 60,000 members.

Caring about children is a basic maternal, paternal, familial and societal urge. Why is it that children collectively have a low priority with us as a nation? Health expenditures, for instance, in Great Britain are 119% of the prime age adult level for each child. In the United States, the ratio is only 37%. The budget for the National Institute of Child Health reflects this dismal perspective.

"Learning Disabilities" which is defined differently among professionals generally refers to learning and behavior dysfunctions presumed to be central nervous system related. Currently, the concomitant difficulties is social competence are seen to be equally or more crippling to life adjustment than the dyslexia, hyperactivity and school problems previously perceived as critical. As awareness of learning disabilities has increased, the federal response has been to have the Department of Education simply put a cap of 12% on the number of children who could be identified for services in schools. A longer range plan we urge Congress to consider is to develop a national initiative on parental prevention covering all developmental handicaps.

The National Institute of Child Health and Human Development (NICHD) has already invested time developing a strategic plan to identify and document low birthweight and pre term birth factors, but funds were not available to continue the project. Just last August, Pediatrics (Vol. 76, No. 2) reported on a 12 year French intervention study with a program for prevention of pre term deliveries and low birthweight. The study showed that consistent reduction of these undesirable outcomes is feasible. The cost effectiveness follows automatically with reduced intensive care nursery costs and statistically reduced long term impairments such as nuerologic handicaps and developmental disabilities with all their consequences.

Studies show that, at its current rate of progress, this nation will not meet the Surgeon General's 1990 low birthweight goals, either for all races or for non-white infants. A March of Dimes supported study found that premature births cost $100 per hour per child in intensive hospital services. For all low birthweight infants the risk of nuerodevelopmental problems is three times that of normal birthweight infants. For very low birthweight infants the risk is ten times that of normal infants.

Low birthweight is not the only factor that NICHD could profitably address in reducing prenatal insults with long term results, but it is of critical concern for reasons of humaneness, conservation of human potential and reducing national expense in the long term. This aspect has already been proven in other countries and is of great concern to all those whose children, able or disabled, will be saddled with the national debt.

Another area of NICHD responsibility which our Association views as urgent is aggressive inquiry regarding toxins and environmental factors which affect the vulnerable developing brain in utero and early childhood. Some of the mechanisms of lead and mercury in damaging the central nervous system have been documented. We see urgent need for increased attention to the effects of numbers of chemicals proliferating in our environment to which the very young and old will be especially susceptible.

We urge you to provide a current services appropriation for NICHD. By insuring that our babies arrive healthy and intact you will be improving the potential of tomorrow's citizens and also insuring a fiscal benefit over the next decade.

STATEMENT OF JOHN F. GOGGINS, D.D.S., AMERICAN ASSOCIATION FOR DENTAL RESEARCH

Senator PROXMIRE. Our next witness is Dr. John Goggins, American Association for Dental Research. Dr. Goggins is from the No. 1 State in this country. [Laughter.]

Dr. GOGGINS. A great city and a great lake. That is our motto.

Senator PROXMIRE. Marquette University. I am really proud of Marquette. It is a fine institution.

Dr. GOGGINS. Thank you, Mr. Chairman. My name is John Goggins. I am the dean at Marquette University School of Dentistry in Milwaukee. I am here representing the membership of the American Association for Dental Research to present our views on the 1987 budget for the National Institute of Dental Research.

We have a prepared statement which we are submitting for the record, but I would like to take just a moment to emphasize a few of the points that we have in our statement. The first point I wish to emphasize is the remarkable success we have had in dental research. Earlier witnesses have talked about prevention as a goal in research. I think clearly, the dental research community has addressed this, and there are many of our preventive procedures that are now out there and reaping the benefits.

The record of our research speaks for itself. Today, many fewer children are subjected to the carnage of rampant decay, and adults may expect to retain their teeth into old age. What I am really speaking of here goes beyond health, but it really is a major impact on the quality of our lives. Good oral health contributes so much to that quality. So we have a lot to do, and we are going to have to continue to place a major emphasis on the basic and clinical sciences in dentistry.

In order to do this, we are going to have to be sure that there is a continual influx of bright young minds into this effort. We have. There is a dentist scientists program which is designed just to accomplish this. The program provides for advanced basic and clinical development of science and scientists as well as provides an opportunity for the further development in meaningful research.

The program is designed to develop those very special individuals that serve as the link between the basic science laboratory and application of the basic science findings and the clinical setting.

Another point I wish to emphasize is that while the regular research grants are the backbone of our research efforts and should be increased, the President's budget does not really adequately address the need or the role of centers of excellence in research. Centers bring together individuals from differing disciplines to focus their talents on specific subjects. In this kind of a research atmosphere, the productivity is much greater than the sum of the parts, the enhancement of research by bringing a variety of disciplines together.

I think the committee, I would hope, would take a look at this area. Our prepared statement has some more specific recommendations along these lines, and for the sake of time, I won't go into those. I would like to say that we, as the American Association for Dental Research, recommend a funding level for the National Institute of Dental Research of $115 million.

I have one final point that I would like to emphasize; that is the fact that the President's budget eliminates funding for biomedical research support grants. These grants have been likened to the oil that keeps the machinery of research running smoothly. They provide institutions with the ability to conduct pilot studies and to meet sudden, unanticipated research opportunities.

PREPARED STATEMENT

Therefore, we recommend that this program be restored in the NIH budget. I would like to thank you for your time, Mr. Chairman, and I will be happy to answer any questions that you may have.

[The statement follows:]

Statement of John F. Goggins

Mr. Chairman and members of the committee: My name is John Goggins. I am Dean of the Marquette University School of Dentistry in Milwaukee, Wisconsin.

I am appearing before you today on behalf of the American Association for Dental Research (AADR). The members of the Association appreciate having this opportunity to present testimony regarding the 1987 budget for the National Institute of Dental Research.

The membership of the AADR consists of over 4,000 scientists from a variety of basic science and clinical disciplines located in universities, research institutes, hospitals, and industrial laboratories around the country. Our principal objective is to study the causes of the major diseases affecting the teeth and oral/facial region, and to seek ways of controlling and/or preventing these diseases.

Scope of Dental Science

The field of dental research involves basic and applied research related to the causes, prevention, and methods of diagnosis and treatment of oral diseases and conditions. The areas of research pursued by dental scientists include the following:

- caries (tooth decay)
- periodontal diseases (gum diseases)
- oral cancer and other soft tissue lesions
- congenital craniofacial anomalies
- temporomandibular disorders
- taste and smell disorders

* pain
* AIDS
* herpes
* salivary glands
* biomaterials

The research on these disorders requires a wide range of scientific disciplines working in a variety of extramural and intramural settings. The work currently supported by the National Institute of Dental Research covers the full spectrum of research activities required to understand, treat, and prevent oral diseases -- such as basic, applied, and clinical research, technology transfer, and training of the next generation of research scientists.

Statement of Problem

Mr. Chairman, as you know, most Americans experience oral diseases of some form from early childhood until death. In fact, oral and dental diseases constitute, in the aggregate, the most prevalent health problem in the Nation.

The monetary cost to society as a result of oral disease is high. In 1984, according to the Department of Commerce, Americans spent $19.8 billion for dental services. To this figure must be added the time lost from work, estimated to be 32 million days, and reduced productivity caused by pain and discomfort.

With the aging of our population, we are beginning to see more of our senior citizens experiencing caries on the root surfaces of their teeth. As people age, the gums around the teeth recede, exposing the root surfaces, thus permitting bacteria to attack those surfaces. When this occurs, the roots are destroyed much more rapidly than are tooth crowns, leading to sudden and serious problems in tooth retention.

In addition to the specific problems of the elderly, there are many other areas requiring continued research attention -- for example, the number of babies born with facial deformities, and the high incidence of oral sores caused by the herpes simplex virus. As you can see, oral diseases affect every age group in our society.

Research Achievements

Dental science has yielded new discoveries which point to important new preventive measures for oral diseases. For example:

* Periodontal diseases: Studies of unique forms of periodontal disease are contributing to better understanding of the pathogenesis of and immune responses to these diseases. Defective polymorphonuclear (PMN) white blood cells have been shown to be an important factor in juvenile periodontitis (JP), a severe form of periodontal disease that runs in families. The PMN cells fail to migrate rapidly to the sites of infection. This failure has now been attributed to the absence of a single cell surface protein. Lack of this protein in a child in a family with JP might also indicate that the child is at risk for the disease. A newly defined syndrome which affects young children, pre-pubertal periodontitis, also appears to involve PMN defects -- in this case, complete inability of the cells to migrate to the site of

infection. Other studies have explored the reasons for the fact that diabetic patients are highly susceptible to periodontal diseases. One study found reduced cellular uptake of ascorbic acid in the cells of diabetic patients, compared to similar uptake in cells of normal patients.

* Soft tissue diseases: Three approaches to controlling herpes simplex virus infections are under study. The first approach is prevention through the use of a genetically engineered vaccine composed of a herpes simplex virus cell surface antigen gene and the vaccinia virus. In experiments conducted a year ago, this vaccine proved effective in protecting mice against both herpes simplex virus type 1 (oral) and herpes simplex virus type 2 (genital) infections. The second approach is designed to alleviate herpes simplex virus infection. When administered prophylactically on a daily basis, the drug acyclovir has been shown to reduce the frequency of reactivation of genital herpes. A third approach is aimed at identifying the processes involved in triggering reactivation. These studies have implicated ultraviolet light as a trigger and are allowing investigators to study the early skin changes that precede overt herpes lesions.

* Caries: Work continues on understanding the multiple mechanisms by which fluoride protects developing enamel and assists in remineralizing early caries lesions. Efforts to reduce the prevalence of caries beyond levels already achieved are emphasizing studies of oral ecology and immunology. Scientists are testing the feasibility

of blocking mother-to-infant transmission of _Streptococcus mutans_, considered to be the principal cause of tooth decay, by using non-virulent strains to co-opt colonization sites in erupting teeth. On-going immunological studies are focusing on improving understanding of secretory immunity and studying a variety of candidates for an anticaries vaccine. Also, public awareness of caries-preventive measures appears to be growing, as reflected in the increased demand for and provision of dental sealants by the profession for the prevention of decay on occlusal surfaces.

- _Restorative materials_: In a 5-year clinical study, researchers are testing new adhesive materials and methods of application that will permit bonding of restorative materials to both dentin and enamel. Also under investigation is the feasibility of using sealed composite restorations to arrest caries lesions without cavity preparation and without removal of the lesion material. Such treatment is unlikely to require anesthetic injection and also conserves tooth structure. Further, the sealed composite restorations are being compared to standard amalgam restorations.

Dentist-Scientist Award

Members of the committee: If research momentum is to be maintained, then continued attention must be given to ensuring the future availability of a variety of investigators to staff dental schools and dental research institutes. In the past two appropriations bills, this committee has provided support for the Dentist-Scientist Award, and we in the community deeply appreciate your support. However, in order to continue the work you have begun, we respectfully request that an additional $1,500,000 be provided for this program in 1987.

There are three components to the Dentist-Scientist Award program, namely:

- Advanced Basic Science Development: To develop requisite knowledge and research skills in needed basic science areas.

- Advanced Clinical Science Development: To ensure that the candidate has the requisite advanced clinical knowledge and skills.

- Research Experience Development: To provide an intensive research experience that will facilitate the individual's transition from trainee to active investigator.

Centers

Mr. Chairman, an important tactic in the strategy for solving oral health problems has been the establishment of centers to focus research efforts on specific disorders, such as periodontal diseases and tooth decay. This type of multi-disciplinary and concentrated approach will accelerate development of needed information as well as coordinate the application of all dental research findings toward the prevention and cure of dental diseases. At present, centers for pain and oral biology are under consideration. However, additional centers are needed for geriatrics, restorative dentistry, temporomandibular joint problems, and core grant programs to provide common research equipment and administration for the individual grantee. In short, these centers fill an important gap in the program of dental research, and thus, the committee is urged to provide funding for an additional six centers.

Budgetary Needs for NIDR

The investment of the public's funds in the research programs of the National Institute of Dental Research is, and has been, paying dividends. One has only to look at the reduction in the prevalence of dental caries and the expanding knowledge base about the causes of periodontal diseases to see the rate of return on the investment made to date. We believe that through your continued support the dental research community can and will make significant progress toward solving the multitude of oral diseases confronting our society.

Unfortunately, Mr. Chairman, the President's 1987 budget for the National Institute of Dental Research is not adequate to maintain the current program level, nor will it permit the Institute to expand significant and promising areas of research.

While we are fully aware of the difficult budgetary pressures facing the Congress, we believe that adequate funding for the Nation's biomedical research enterprise can be achieved through a re-ordering of the priorities in the President's budget. It is with this in mind that we respectfully request a 1987 funding level for the National Institute of Dental Research of $115 million. This level will allow for a balanced research program in dental science.

Mr. Chairman, this concludes my testimony as it relates to the National Institute of Dental Research. At this time, I would like to take the opportunity to address three additional program areas which provide important support for the research conducted and supported by NIDR.

Specifically, I would like to call your attention to the Biomedical Research Support Grant (BRSG) program, which is being proposed for elimination in the President's budget. This program is designed both to meet emerging opportunities in research on and pursuit of new ideas, and to develop young scientific talent. The BRSG has become an important part of the dental research effort in this country. We believe the loss of this program will weaken institutional research in the health sciences. Therefore, we urge the committee to restore this program to at least its 1986 level.

A second area of concern is that we must continue obtaining adequate information on disease status in order to direct research appropriately. For this, the support of the National Center for Health Statistics is of vital importance, and it should be funded accordingly.

Third, and finally, to ensure the most effective implementation of dental research findings, the National Center for Health Services Research and Health Care Technology Assessment provides a vital role, and we urge adequate funding for this Center as well.

Thank you for this opportunity to testify, and I will be happy to answer any questions.

Senator PROXMIRE. Thank you very much, Dr. Goggins. As I say, I am delighted that you are here. It is good to have a Wisconsin Badger witness. I must say, your testimony is anything but self-serving. It seems to me that as we perfect preventive strategies to reduce tooth decay and periodontal disease, for example, we will be reducing the need for dentists and, consequently, the enrollment at the Marquette School of Dentistry.

Dr. GOGGINS. The enrollment, as Dr. Kennedy said, the enrollments are falling. This is part of the free market system to live with. I think it is an important thing to note that the Federal Government is not funding programs to increase enrollment in dental schools but, rather, to improve oral health. So we are not asking for anything to increase enrollment. There are many diseases and disorders of the oral cavity that are not receiving enough attention and practice.

There are economic cycles to denistry, just as there are to engineers to education and to anything else. Right now we are seeing a downturn in the economic cycle. In response to this, there are fewer applicants to dental schools and the dental schools are cutting their enrollments.

I think the research advances are not going to eliminate the need for dentistry, clearly. They are going to only provide the dentists with better tools to provide a better life for their patients. That was a point I wanted to make particularly in oral health, because the quality of life, the mouth is a very important part of our being, both physically and psychologically. To have a healthy mouth is a big contributor to our mental health and the quality of our life.

Senator PROXMIRE. We in the Senate are experts on the big mouth. [Laughter.]

I want to thank you very, very much for your fine testimony. Unfortunately the day will never come, I am sure, when we are able to prevent all these diseases and illnesses, and we will always need dentists.

Dr. GOGGINS. This is the idea of the profession, is to do away with the need for itself. Thank you, Mr. Chairman.

STATEMENT OF WILLIAM ALLEN, D.D.S., DIRECTOR, AMERICAN DENTAL ASSOCIATION (DISTRICT OF COLUMBIA)

Senator PROXMIRE. Thank you. Our next witness is Dr. William Allen. Dr. Allen is director of the American Dental Association.

Dr. ALLEN. Good morning, Mr. Chairman. I am Dr. William Allen. I am the director of the Washington office of the American Dental Association. I am representing them and the American Student Dental Association. I am only sorry I didn't go to Marquette.

Senator PROXMIRE. So am I.

Dr. ALLEN. We would like to submit our testimony for the record. I would just like to make a few brief comments.

Senator PROXMIRE. It will be printed in full.

Dr. ALLEN. We are very appreciative of the foresight of the Congress, particularly in the last 25 years. The National Institute of Dental Research has been funded, and we think there has been significant progress in the reduction in dental disease. We are now realizing, as you mentioned before, there has been a great reduction in dental care for children, and as a former practicing pediatric dentist for 35 years, I can tell you that dental care no longer is a major important item in children.

However, we still need to continue research, in my opinion, because we really don't know as much about dental care in the adult population, and particularly the elderly, which is obviously the fastest growing section of our society. So we would really hope that we would be able to develop some research into what causes periodontal disease and other oral infections in the adult and the elderly population. This would be, certainly, a major accomplishment.

I think we are possibly on the threshold of a major breakthrough in dental research as a result of new developments in genetic engineering and immunology. If adequately funded, it may be possible to provide information and to develop techniques to actually determine who is likely to develop dental disease or periodontal disease.

In as much as these are infectious diseases, treatment and modalities could be developed that treat these conditions with chemical or other nonsurgical intervention and to destroy these disease organisms. This, of course, would be a major breakthrough from the standpoint of patient care.

NIDR continues to play an important role in assessing the effectiveness of treatments in the clinical setting. So often, research is directed at basic research and has no application of the clinical practices, but this is not the case at NIDR. They have been in the forefront of developing techniques that are directly applicable to patient care such as sealants; composite restorations; they are doing studies on implants, all of which would allow us to treat patients more effectively.

So we, too, would urge that the funding level of $115.9 million in fiscal year 1987 be included. The biomedical research grant, as reported by Dr. Goggins we think, is an important aspect and allows dental schools to do innovative research and to support new investigators.

Also, as you pointed out, dentistry has been accused of trying to do away with itself, but we would like to support the inclusion of the dental disease preventive activity of the Center for Disease Control. This activity provides a national focus for control and prevention of oral disease such as dental care, periodontal disease, oral cancer, and also provides technical services to State and local governments and other citizens organizations.

Last, I guess we would like to support the testimony of Dr. Kennedy on the real need for student loans. I have been on the Board of Regents for our university and last year, for a 3-year school, we set our tuition rate at $21,000. This is for tuition alone. So the indebtedness here for a student graduating from the school is tremendous.

We would like to particularly urge that the HEAL loans be continued. This is the loan of last resort for many students, and as a result, this is the only place they have to turn to. As one who went to school from a middle income family, we think is an avenue that really needs to be included. While it requires no Federal outlays, we would like to see language in the appropriations bill that would include this.

We thank you very much.

Senator PROXMIRE. Thank you very much, Dr. Allen. You are asking for a substantial increase, but I think you certainly make a very good case for it. The fact that there has been such marvelous progress in dental research is a great blessing for all of us, although it has an effect on the economics of the dental profession. I think there isn't anything but good coming from it.

On page 5 of your prepared testimony you make a very good case, as you did in your presentation, on the fact that black dentists now represent only one-third of their proportion in the general population. Hispanics have about the same kind of deficiency. On the other hand the income of people who go to dental school is about 30 percent higher than the average income of the population as a whole so people who are less affluent and anxious to become dentists should have an opportunity to do so.

On page 11, you recommend a $460,000 budget for the chief dental officer. What is his current budget?

Dr. ALLEN. There is no current budget, in my understanding, for the office. There has been a line item, but I don't think the office has been filled. This, I think, would be a source of at least identifying a chief dental officer in the Public Health Service who people could look to. It has been authorized but it was abolished, and we would like to see it restored to give some focus to the public health sector.

PREPARED STATEMENTS

Senator PROXMIRE. Thank you very much, doctor.

Dr. ALLEN. Thank you.

Senator PROXMIRE. Your statement will be included in the record at this point along with other statements submitted for the record on appropriations for the National Institute of Dental Research.

[The statements follow:]

STATEMENT OF WILLIAM ALLEN

My name is Dr. William Allen. I am Director of the American Dental Association Washington Office. I am appearing today on behalf of the American Dental Association and the American Association of Dental Schools. This morning I would like to highlight the major areas of concern to our Associations and, with the permission of the Subcommittee, submit a more detailed statement for the record.

Dental Research

In the past decade impressive progress has been made in the prevention and control of dental disease. Dentistry's effectiveness in improving the oral health of the public is demonstrated by the dramatic reduction of caries in children and the increased retention of natural teeth in adults. These extraordinary health benefits to the public were made possible by the continued expansion of dental research. The progress made towards understanding the biology of the mouth promises that other dental diseases, such as periodontal disease and herpes simplex, can be brought under control before very long if funding for the National Institute of Dental Research (NIDR) remains adequate.

The NIDR remains committed to achieving even greater reductions in dental caries than have already been accomplished. Emphasis must now be put on tailoring prevention and treatment to individuals at high risk of developing decay, such as the handicapped, patients who have weakened immune systems or the elderly. Continuing research in these areas is vital to dentistry as it turns toward the challenge of preserving natural teeth for a lifetime. Sufficient funding is needed to attract dental researchers to carry out this work.

The proportion of dentists involved in research has drastically declined because the prospects for a career in dental research are so tenuous. A 1985 Institute of Medicine study reported that "full-time basic science faculty at dental schools declined by over 6 percent since 1982." NIDR's Dentist Scientist Award was established in 1985 to reverse this trend, but funding cuts are now endangering this very successful program. Originally, NIDR had planned to support 170 dentists in this program by 1989. However, current levels of funding allow no new candidates to be added to the program which only has 33 candidates.

Congress appropriated $103.3 million for NIDR for FY 1986. As a result of Gramm-Rudman, NIDR lost $4.5 million from its 1986 appropriation. The President has asked that even further reductions be made in 1987, shrinking NIDR's budget to $96.5 million, an additional loss of $6.8 million. Furthermore, if the President's budget is adopted the number of new and competing dental research grants would be cut from 149 to 110. Our Associations believe that in order for NIDR to maintain its current quality of dental research, it needs a minimum budget of $115.9 million for FY 1987.

The dental profession also urges the Committee to restore full-funding of the Biomedical Research Support Grant (BRSG) program. The President's budget cites this as a low priority program and proposes to begin phasing it out in FY 1987 with a $60 million funding cut. The BRSG program is vital to the dental research community. It is used by research institutions to support pilot studies, buy critically needed equipment, provide early research support to new investigators and fund new and emerging research opportunities. Dental schools with small research programs would be particularly hard hit.

Student Aid

Our Associations are most concerned that the limited funding provided to health professions education in recent years will result in reduced access to the health professions for qualified students from non-affluent backgrounds. The decline in federal support for health professions education has paralleled an increased reliance on families to pay the costs of attending dental school. In 1978, the average dental student's parents had a family income 12 percent higher than the national median family income. Dental students graduating last year came from families with incomes 30 percent higher than the estimated median family income of $28,000.

During this same time, the percentage of black students enrolled in dental schools remained level, but well below desired levels. While blacks represent 12 percent of the U.S. population, they made up only 4 percent of the 1985 graduating dental class. A similar situation exists for Hispanic students who made up only 2.8 percent of the 1985 class even though Hispanics comprise 6.5 percent of the population.

We believe that unless this decline in federal support for health professions education is halted only students from affluent backgrounds will be able to attend dental schools. Furthermore, we fear that the number of minority students graduating from dental schools will continue to fall below desired levels. Proper resources are necessary to see that this doesn't happen.

Mr. Chairman, since 1981 health professions education funding has declined by $38 million. When adjusted for inflation, this represents a 35 percent decrease. These significant reductions have occurred during a time of increased demands for primary care training, recruitment and retention of disadvantaged students, and geriatric initiatives. Our Associations urge the Subcommittee to fund health professions education programs at the full authorized amount of $144.9 million.

Although the Health Education Assistance Loan (HEAL) program requires no federal outlay, we are very concerned that the HEAL program remain a viable "loan of last resort" for dental students. Last year, approximately 4,600 dental students borrowed over $47 million through the HEAL program. We ask your assistance in assuring continued access to the HEAL program by inserting language in the FY 1987 appropriations bill that will address the following concerns:

1. Access to HEAL loans should be guaranteed up to the auhorized limit of $290 million plus any unused amount carried from prior years.

2. The total amount of HEAL credit authority should be required to be granted without apportionment or other similar limitations.

3. The Department of Health and Human Services should be directed to issue the proposed regulation on the HEAL program immediately.

We are aware that there has been concern about defaults on HEAL loans. ADA and AADS have made this a top priority. I am pleased to report that the representatives of our associations have formed a task force to work with officials from HHS. We are attempting to determine the severity of the problem and to develop strategies for prevention and reduction of HEAL defaults. We are confident that by working with schools, lenders and the Administration, a significant improvement can be achieved.

Dental Disease Prevention

Our Associations believe that the Dental Disease Prevention Activity (DDPA), of the Centers for Disease Control, continues to provide a national focus for the control and prevention of oral diseases and conditions such as dental caries, periodontal diseases and oral cancer. This valuable national role includes providing consultation, training, promotional and educational support, disease surveillance, and other technical services to state and local governments and other professional, educational, and citizen organizations. Additionally, it has assumed a key leadership, support and coordinating role in promoting heightened standards and practices for infection control in dentistry.

The DDPA works very closely with the American Dental Association and other major health organizations on an on-going basis and serves as a key advisor to the ADA Council on Dental Health and Health Planning, the Council on Dental Therapeutics, and the National Fluoridation Advisory Committee. In addition, the DDPA is co-sponosoring with the Association the 1986 National Conference on Infection Control in Dentistry, to be held in Chicago, May 13-14.

The continued involvement of the DDPA with the ADA in many areas of mutual interest is critical if the dental well-being of the American people is to be best served. The prevention of dental diseases has consistently been shown to be a good investment. Without a doubt, dental disease prevention efforts in the past have prevented much illness and functional disability and greatly enhanced the quality of life for the American public. In the process, many billions of dollars worth of repair and rehabilitation costs have been averted.

Our Associations believe that the 1987 appropriation for DDPA should be $1,196,900. This would allow the DDPA to continue ongoing critical services that have been essential for disease prevention.

National Center for Health Statistics (NCHS)

Last year, Mr. Chairman, we testified on behalf of increased funding for the National Center for Health Statistics

(NCHS). As you know, NCHS is the principal Federal agency for monitoring health status and its relationship to other factors, and we appreciated the increased funding Congress appropriated for NCHS last year.

During 1986 the Center will collect important data about visits to dentists, personal preventative dental practices and current public knowledge of risk to dental disease. These data are needed to organize and target preventative care dental programs to the appropriate populations. NCHS must have the capacity to make timely and thorough analysis of these data, as well as those collected by other recent surveys, if they are to yield a return on the investment made in data collection.

Funds are needed in FY 1987 to prepare for the third cycle of the National Health and Nutrition Examination Survey (NHANES III) so that data collection can begin in 1988 as scheduled. From these data and others collected by this survey, the prevalance of major oral diseases and conditions, critical personal and social characteristics associated with oral health, the social impact of dental diseases and the relationship between oral and general health can be studied, thus providing a comprehensive approach to the measurement of health.

The dental profession believes that the Center should be supported in 1987 by $70 million. This funding level would allow NCHS to continue annual survey activities of sufficient depth to be useful to all major sectors of the health field.

OFFICE OF THE CHIEF DENTAL OFFICER

The position of Chief Dental Officer, of the U.S. Public Health Service is authorized by Congress in law. But in 1981 the Office of the Chief Dental Officer was abolished by the Department of Health and Human Services and the duties of the Chief Dental Officer were assigned to the Chief, Dental Services, Indian Health Service (IHS). This unilateral action has severely compromised the effectiveness of the chief dental officer.

ADA and AADS believe that the Office of the Chief Dental Officer should be included in the budget for the Office of the Assistant Secretary for Health as a separate line item. We believe that a budget of $460,000 is necessary to properly establish and properly staff this office.

As the Public Health Service's lead dentist, the Chief Dental Officer identifies oral health issues and proposes strategies to the directors of PHS agencies centers and offices, develops and recommends proposals for PHS oral health policies and positions, advances dental issues of PHS-wide significance, represents the position of the Service before national dental organizations and other Federal agencies and serves as the principal contact for oral health matters with dental public health counterparts in state health departments, other countries and the World Health Organization. As you can see, Mr. Chairman, the Chief Dental Officer has an important role in the Service, and to expect him to carry this out without any legitimate office or assistance is unfeasible.

Mr. Chairman, this concludes our statement.

STATEMENT OF THE AMERICAN DENTAL HYGIENISTS' ASSOCIATION

Summary of Recommendations:

The American Dental Hygienists' Association (ADHA) recommends that, for FY 1987, the National Institute of Dental Research (NIDR) receive an appropriation of $119.4 million. The funding request is consistent with the overall recommendations for the National Institutes of Health (NIH) prepared by the Ad Hoc Coalition for Medical Research Funding which recommends $6.1 billion for NIH in the upcoming fiscal year. ADHA endorses the Ad Hoc Committee Recommendations as well.

The National Center for Health Services Research and Health Care Technology Assessment should receive an appropriation of $21 million; the Community and Migrant Health Centers should be appropriated $400 million and $45.4 million, respectively, consistent with authorized levels; the National Health Service Corps should receive $75 million; and the Congress should indicate its desire that the Director of the Centers for Disease Control (CDC) fund the Dental Disease Prevention Activity (DDPA), at $1.3 million through the Director's discretionary budget.

The American Dental Hygienists' Association (ADHA) appreciates this opportunity to present its views with regard to the FY 1987 Appropriations for the Department of Health and Human Services (HHS). Organized in 1923, ADHA represents 30,000 members across the country dedicated to assuring the highest level of preventive dental care. Originally formed to develop communication and mutual cooperation among the hygienists, ADHA today serves as an advocate for dental hygienists at the federal, state and local levels. Nationally, ADHA is divided into 12 districts.

ADHA's mission, "to improve the public's total health by increasing the awareness of and access to quality oral health care and to position the dental hygienist as the preventive oral health professional," reflects the professional goals of ADHA's membership. The foremost prevention professional on the dental care team, dental hygienists are licensed providers. Hygienists provide educational, clinical and therapeutic services supporting total health through the promotion of optimal oral health. Our members are responsible for providing treatment that helps prevent oral disease such as dental caries (cavities) and periodontal disease (gum disease).

The hygienist's prevention services are provided in a number of places. One most commonly thinks of a hygienist in the dentist's office or in a dental clinic. Hygienists also work with federal, state and local health departments, in hospitals and nursing homes, school districts, correctional facilities and institutions for individuals with special health needs. Just as the hygienist is located in a variety of work sites, so too, the role of the hygienist in dental practice is varied. Hygienists monitor patients' health histories; examine teeth and oral structures; remove calculus, stain and plaque; apply caries-preventive agents such as fluorides and fissure sealants; develop individualized oral hygiene programs for home care; expose, process and interpret dental-x-rays; place temporary fillings and periodontal dressings; remove sutures; polish and contour amalgam fillings; and educate the individual about the importance of good oral hygiene habits.

THE STATE OF AMERICAN DENTAL HEALTH

The role of these activities in achieving good dental health is impressive. We are witness to a fifty-percent decrease in tooth decay; one third of American grade-school children are caries free. Indeed, research scientists now suggest that elimination of most major dental diseases may be possible within the lifetime of oral health professionals now practicing.

But we have not yet achieved this ultimate goal — indeed we are far from it:

- Overall, Americans are spending $20 billion a year for treatment of their dental and oral problems;
- American's lose 32 million days of work due to dental problems, costing the American economy $3 million in lost wages. Amazingly, this economic statistic does not even include losses in productivity;
- 23 million Americans are missing all of their teeth;
- Despite reductions in dental caries, the average American child has at least one caries lesion by age 8; 4 by age 12 and 11 by age 17.

Counterbalancing these gloomy figures is the promise of prevention. Research has shown that at least one form of dental caries (coronal caries which attacks the crowns of teeth) is preventable. Moreover, the National Institute of Dental Research (NIDR) Long-Range Research Plan for FY 1985-89 has stated that, "fluoride regimens and adhesive sealants, combined with good oral hygiene and wise eating habits, can prevent tooth decay in normally healthy individuals." Herein lies the true value of the hygienists' mission: as the lead advocates, spokespersons and educators in preventive oral health care, we can do something about preventable disease today. Indeed, the NIDR's long-range plan recognizes this, stating:

> Dental hygienists are of particular importance in caries-prevention procedures since these individuals play a major role in patient education and instruction. There should be ample opportunities to investigate their use to foster patient education about fluoride and to promote caries-prevention activities in general.

In battling preventable oral disease, the federal government provides three major services. Knowledge about the causes of dental diseases and preventive techniques can be increased through basic biomedical research. Improved methods of health care delivery can be identified, tested and quantified. Delivery of health care services to populations without adequate access to dental care and dissemination of new techniques can be achieved. In these efforts, the Congress can provide assistance through adequate funding of the National Institute of Dental Research, the National Center for Health Services Research, the National Health Services Corps, the Community and Migrant Health Program and the Centers for Disease Control's Dental Disease Prevention Activity.

NATIONAL INSTITUTE OF DENTAL RESEARCH (NIDR)

Founded in 1948, NIDR, one of the 2 major biomedical research institutions within the National Institutes of Health, has helped to revolutionize our knowledge and provision of dental health care. In identifying the causes of preventable dental diseases and the appropriate strategies to combat these maladies, NIDR has led the way. Through NIDR sponsored research, we have:

- o identified the major cause of certain forms of dental caries;
- o validated the importance of flouride in oral health regimens;
- o been able to work towards a vaccine against dental caries;
- o improved adhesive sealants to protect teeth from the ravages of dental caries;
- o identified the link between good nutritional and good oral health; and
- o demonstrated the importance of education, and promotion activities in assuring good oral health.

Despite these successes, the funding for NIDR has not been commensurate with the research need. Although the Long-Range plan indicates a budget need of $135.5 million for NIDR in FY 1987, plan implementation has been slowed, in part due to the recent year budgetary restrictions which have affected all of NIH. Thus, a need-based budget for FY 1987—one which would allow NIDR to proceed with timely implementation of the Long-Range Plan--would provide NIDR with $119.4 million for the upcoming fiscal year.

In contrast, the President's budget would fund NIDR at $96.5 million. Such a low level of support would severely compromise the on-going operation of the Institute. NIDR has already suffered serious budget reductions. Although the Long-Range Plan indicated a need for $105.4 million in FY 1986, the Institute was funded at $103.3, an amount which was further reduced under Gramm-Rudman by $4.5 million. This total cut of 11% severely compromised the Institute's ability to expand our knowledge about how tc fight dental disease. Inexplicably, the budget-cutters at OMB want to sap the NIDR's ability even to compete with inflation. The result would be a reduction in the number of new and competing research grants from 149 to 110 (a cut of over 25%).

Indeed, several major initiatives NIDR was planning to pursue in the upcoming year will be curtailed. These include:

- o Early this year, NIDR, in conjunction with the Veterans Administration and the National Institute on Aging, published A Research Agenda on Oral Health in the Elderly. This historic collaboration targeted the type of research activities most necessary to address the special needs of the elderly. The oral health needs of this population, which will only increase as we move toward the 21st century, must receive prompt attention. These research initiatives would not be funded under the President's budget.
- o A major study of the dental health of the elderly would complement the Research Agenda. Because so much of the dental care provided to

this growing age cohort involves the provision of appropriate preventive care, this study is vital to ADHA's mission. Yet the study would not receive funding under the President's FY 1987 budget.

- A complementary study to assess pediatric oral health problems is under consideration by NIDR. Funding for this study would also be foregone under the President's FY 1987 proposal.
- Programs to identify and educate patients and hygienists about the potential dangers (or lack thereof) of AIDS transmission in the dental office would be compromised.

Thus, ADHA strongly recommends funding of NIDR at $119.4 million in order to address the vital dental research needs of the Nation.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT (NCHSR/HCTA)

The NCHSR/HCTA, an agency within the Public Health Service, plans, develops and administers a program of health services research, demonstrations and evaluations. Through grants and contracts to private and non-profit organizations, the Center supports projects to address the financing, organization, quality and utilization of a variety of health care services.

Ultimately ADHA is a service delivery organization. As such the mission of NCHSR/HCTA is of vital importance to our work. Although the Center has supported only a limited amount of research related to dental health service delivery, Center officials have indicated a willingness to work with ADHA in promoting dental and prevention related research projects. While we recognize the importance of basic biomedical research and do not intend to allow these research needs to suffer at the expense of other funding priorities, neither can ADHA accept the continued inequity in funding between service delivery and basic research. Ten years ago, the budget of the Center was one third of one percent of the size of the NIH budget. Today the Center's budget is less than one one-three hundreth of a percent of the NIH allocation. An alternative method of comparison would contrast the numbers of research grants at the two institutions. While the Administration has established a target base of 18,000 research grants at NIH for FY 1987, NCHSR/HCTA was able to support only 79 grants in FY 1986, up from 40 grants in FY 1983. It has been suggested that a more appropriate ratio would provide health delivery research and assessment with a funding level high enough to allow NCHSR/HCTA to support about 1% of the number of grants supported in biomedical research.

In order to fund a number of grants more in line with this approach, ADHA recommends support for NCHSR/HCTA at $21 million, $7 million more than was requested in the President's budget submission. Not only would this allow for necessary added expansion in NCHSR/HCTA programs, bringing the Center's extramural grant total up to approximately 140, such a level of funding would be consistent with the greatly expanded mission of the Center as mandated by Congress under PL 98-551, the Health Promotion and Disease Prevention Amendments of 1984.

COMMUNITY AND MIGRANT HEALTH CENTERS

The Community and Migrant Health Centers (CMHC) grant program is designed to support facilities that provide comprehensive, primary health care services as well as preventive and educational programs to medically underserved areas and migrant workers. In order to qualify for Community grants, facilities must meet certain criteria regarding scope and type of services provided, populations served, and the nature of the geographic area to be served. The Migrant grants are awarded to facilities which can best serve the unique needs of migrant workers. Unquestionably, these facilities provide basic health care to a segment of the American public which would otherwise not receive proper health care due to financial, occupational, and/or geographic factors.

As part of their comprehensive, primary care program, all facilities receiving CMHC grants are required to provide preventive dental services. At the present time approximately one half of all CMHCs offer supplemental dental services in addition to their basic preventive services. Additionally, many dental members of the National Health Services Corps (NHSC) are placed in CMHCs in order to fulfill their scholarship obligations. In FY 1985, 181 dental hygienists, provided preventive dental care within these settings.

Because these centers provide important preventive dental care services, ADHA recommends that the CMHC grant program receive funding commensurate with the FY 1987 authorization level as recently enacted (P.L. 99-88). At such levels the Community Health Centers would receive $400 million and the Migrant Health Centers $45.4 million. Moreover, we believe that NHSC should receive $75 million so as to insure the highest level of quality care at the CMHCs.

CENTERS FOR DISEASE CONTROL

The Dental Disease Prevention Activity (DDPA) funded through the Centers for Disease Control (CDC) is a vital support mechanism for state dental health programs. The DDPA provides a national focus for the control and prevention of oral diseases such as dental caries, periodontal disease, and oral cancer. As the national leader in dental disease control and prevention, the DDPA provides consultation, training, promotional and educational support, disease surveillance, and other technical services to state and local governments and other professional, educational, and citizen organizations.

Significantly, in light of the AIDS crisis, the DDPA is spearheading a national effort to promote heightened standards and practices for infection control in dentistry. These standards address the problems of control of AIDS, hepatitis B, and herpes in the dental office. The DDPA also has crucial responsibility in providing technical assistance in flouridation, sealant programs, caries prevention, baby bottle tooth decay, smokeless tobacco and mercury poisoning from dental amalgams. The DDPA is also working with the dental community on the National Fluoridation Advisory Committee and in mid-May the DDPA will co-sponsor the 1986 National Conference on Infection Control in Dentistry.

As the lead proponent of oral disease prevention on the dental health team, the ADHA believes that the mission of the DDPA is a crucial one if the dental well-being of the American people is to be best served. Dental disease prevention has proven to be a good investment. Preventative measures have averted much illness and functional disability, while greatly enhancing the quality of life for the American public. Given the fiscal constraints facing the federal government over the long run, efforts aimed at health promotion with the goal of reducing national health care costs must receive full support. Prevention programs such as the CDC's DDPA have helped save billions of dollars worth of repair and rehabilitation costs in the field of dental health alone. This work must be allowed to continue.

Although the DDPA is not a line item in the President's FY 1987 budget proposal, the CDC appropriation should include funds to allow the Director to allocate $1.3 million for the DDPA. In FY 1986 the DDPA's budget totaled approximately $650,000 million. In 1986 as a result of Gramm-Rudman and other cost-savings measures, the DDPA's ability to promote dental prevention was seriously hampered. The DDPA's virtually non-existent budget for development of education materials has been cut to the bone, so that technical information must be disseminated via verbal communication. In 1986, the administrative budget for technical assistance was also slashed. ADHA's recommendation would allow the DDPA to resume and enhance its mission in education and health promotion—a mission which recently has been sorely neglected.

CONCLUSION

The 30,000 members of the American Dental Hygienists' Association appreciate the contribution this Committee has repeatedly made to improving the quality and availability of dental health care services throughout this nation. We hope that the Committee will continue to support preventive health programs as the most responsible method for long-range reduction in national health care expenditures. In this regard, we hope Committee members will seriously consider these specific funding recommendations and again we appreciate the opportunity to present our views.

STATEMENT OF CAROL A. SCHUTZ, DEPUTY DIRECTOR, THE GERONTOLOGICAL SOCIETY OF AMERICA (DISTRICT OF COLUMBIA)

Senator PROXMIRE. Our next witness is Carol Schutz, deputy director, the Gerontological Society of America.

Ms. SCHUTZ. Thank you for this opportunity to testify.

Senator PROXMIRE. You are from the District of Columbia, is that right?

Ms. SCHUTZ. Right. I don't have a plane to catch.

I am the deputy director of the Gerontological Society of America, a national scientific organization of researchers, educators, and other practitioners in the field of aging. A major concern of the society is the development and application and knowledge in all areas of aging.

My testimony today is on behalf of the society and is directed specifically to the fiscal year 1987 budgets for the National Institute on Aging, the Center on Aging at the National Institute of Mental Health and the title 4 programs at the Administration on Aging.

Despite some recent comments in the media to the contrary, the aging in our society is both a success story and a challenge. More people are living longer, and the quality of life for increasing numbers of elderly are better than that for previous generations. Much of this progress can be credited to all the successful advancements made by past and present generations in addressing the problems across the life force including investments in research.

While these trends are proof of success, they also present a new and multidimensional challenge. The challenge includes: preventing, postponing, and limiting and managing the functional disabilities associated with the chronic illnesses that often accompany old age, especially the old, old, the advanced old age; and finding ways to meet the income and health care needs of the elderly through both individual effort and private and public sector programs; slowing down the expected rate of increase in costs, especially health care costs; and developing new ways to increase the likelihood that years being added to life expectancy are both satisfying and productive.

Finally, this challenge involves and, indeed, cannot avoid doing all of this while improving the quality of life for all members of society, regardless of age.

Investing in research on aging is one of the principal ways of responding to this challenge and of charting the course of an aging society. Because an aging society is a new phenomenon, there is little experience to guide future reactions. Public and private decisionmakers need information about demographics, economic, health, and other trends among the elderly; the kinds and levels of needs for services of personnel. The kinds and numbers of the greatest importance is the need for new knowledge which may alter some of the less attractive aspects, particularly functionally disabled elderly.

While current cohorts of the elderly often benefit directly from such research, indirect benefits also accrue to persons of all ages. These benefits include decreased health care costs to taxpayers and reduced caregiving costs, financial, emotional, and physical to families who provide support to older relatives.

One of the examples of this is osteoporosis, which is most noticeable among postmenopausal women. But through research, we have certainly found that exercise, diet, and other things help women of all ages.

Some research may benefit only future cohorts of the elderly. However, this is a legacy to future generations, and in a very fundamental way, research on aging is an intergenerational transfer of great benefit to persons of all ages as well as those yet to be born. It is an investment in our common future. Funding for the National Institute on Aging under the administration's proposal would be reduced from $156.5 million in fiscal year 1986 to $145.8 million in fiscal year 1987, a 7-percent reduction.

NIA's training program is slated for a 7.2-percent reduction in 1987, while the National Institute of Mental Health's clinical training program would be totally eliminated. The title 4 program under the Older Americans Act would be severely reduced under the administration's proposal, which calls for a 50-percent reduction.

In conclusion, I have outlined the demographic trends and the new and multifaceted challenges they will present, particularly to you as Members of Congress. Key decisionmakers such as yourself will need up-to-date information to effectively chart and respond to an aging society.

Congress has clearly demonstrated an understanding of gerontological and geriatric training through its support in the past, and the programs that have already been funded are beginning to make major advancement. Their potential for making significant contributions in the future is great. The momentum cannot be slowed.

PREPARED STATEMENT

Recognizing the tight fiscal constraints facing Congress in 1987, the society urges that you at least continue the programs at their current levels. These investments in research and training programs may ultimately benefit us all through such indirect benefits as decreased health care costs and a healthier old age.

Thank you.

[The statement follows:]

STATEMENT OF CAROL A. SCHUTZ

Chairman Weicker and distinguished members of the Subcommittee, I am Carol Schutz, Deputy Director of The Gerontological Society of America. The Gerontological Society is the national, scientific organization of researchers, educators, and other professionals in the field of biology, clinical medicine, the behavioral sciences, and social research, policy analysis and planning. A major concern of the Society is the development and application of knowledge in all aspects of aging.

My testimony today is on behalf of the Gerontological Society and is directed specifically to the FY 1987 budgets for the National Institute on Aging, for the Center on Aging at the National Institute of Mental Health, and the Title IV program of the Administration on Aging.

Despite some recent comments in the media to the contrary, the aging of our society is both a success story and a challenge!

More people are living longer. The quality of life for increasing numbers of elderly people is better than that for previous generations. Much of this progress can be credited to all the successful investments and advancements made by past and present generations in addressing the problems across the life course, including investments in research.

While these trends are proof of success, they also present a new and multidimensional challenge. This challenge includes 1) preventing, postponing, limiting, and managing the functional disabilities associated with the chronic illnessess that often accompany old age, especially advanced old age; 2) finding ways to meet the income and health care needs of the elderly through both individual effort and private and public sector programs; 3) slowing down the expected rate of increase in costs--especially health care costs--associated with a growing older population; and 4) developing ways to increase the likelihood that the years being added to life expectancy are both satisfying and productive. Finally, this challenge also involves--and indeed cannot avoid--doing all this while improving the quality of life for all members of society, regardless of age.

Investing in research on aging is one of the principal ways of responding to this challenge and of charting the course of an aging society. Because an aging society is a new phenomenon, there is little experience to guide future actions. Public and private decision makers need information about 1) demographic, economic, health, and other trends among the elderly;

2) the kinds and levels of needs for services these trends will create; and 3) the kinds and numbers of personnel required to meet these needs. Of greater importance is the need for new knowledge which may alter some of the less attractive aspects (e.g., the projected increase in demand and in expenditures for caring for the functionally disabled elderly) and help maximize the opportunities emerging from an aging society. We can better understand the potential returns on such an investment by reviewing some strides research has made thus far in responding to both the challenge of and the opportunities presented by an aging society.

Research in Response to the Challenge of an Aging Society

One clear implication of population trends associated with an aging society is that there will be a greater need for long-term care services for functionally disabled older persons residing both in institutions and at home.

New knowledge may lead to ways of reducing debilitating impacts of chronic illness for some elderly and their families as well as some associated costs to individuals, families, and society. Research on the problem of incontinence, which afflicts an estimated 2.6 to 4.7 million elderly persons (OTA Report), could significantly reduce the number of people in nursing homes and allow some incontinent individuals (who might otherwise have been institutionalized) to remain at home in the care of relatives for a greater length of time (OTA Report). In fact, if research and education efforts have only a 5 percent impact on nursing home admissions during the next twenty years, conservative estimates say nursing home expenditures would be reduced by about $1.125 million per day. Similarly, investments in pharmaceutical and basic research are likely to "provide new therapies for many of the conditions that impair the functional ability of many of today's elderly...[and] lead to significant reductions in the severity of chronic illness among the elderly and in the cost of health care for this growing segment of the U.S. population" (OTA Report).

One area where some progress is being made, but much more is needed, concerns Alzheimer's disease and related dementias. Although "the great majority of people maintain good mental functioning into their later years, the proportions of those who acquire a significant degree of dementia rise rapidly among the very old," with an estimated one in five persons aged 80 and over having a serious, irreversible dementia (T. Franklin Williams testimony, 1983). Moreover, an estimated 30 percent to 50 percent of patients in nursing homes have Alzheimer's disease (OTA Report).

To date, gerontological research on Alzheimer's disease has provided new evidence that the nucleus basalis, the part of the brain that directs brain cells to communicate with one another, is the first area to degenerate ("Special Report on Aging", NIA). In addition, research has 1) shown that carefully structured environments and daily schedules can assist patients and their families in managing this disease; 2) has led to increasing recognition on the clinical level of the absolute necessity of ruling out "potentially treatable causes of dementia before concluding that a person has Alzheimer's disease"; 3) has begun testing the effectiveness of pharmaceutical approaches to treating Alzheimer's (T. Franklin Williams testimony); and 4) has begun to identify the organic basis for the disease.

Between now and the year 2000, an approximately 50 percent increase is projected in the number of nursing home beds needed. Half or more of this increase (T. Franklin Williams testimony) and much more of the increased need for community-based long-term care services are related to the expected needs of persons experiencing severe dementia. Plainly, as a society, we have a major stake in basic and applied research leading to prevention, reduction of incidence, and/or treatment of this and other devastating diseases.

Research in Response to the Opportunities Presented by an Aging Society

The challenge of an aging society also involves developing ways to increase the likelihood that the years being added to life expectancy are satisfying and productive, both for individuals and society. Investing in research 1) can help improve the health of future cohorts of the elderly; 2) can help ensure that the elderly and very old continue to contribute to the development of society through work and community involvement; and 3) can help identify ways the talents of a growing and increasingly better educated older population can serve society.

For example, research has shown that disease prevention, health promotion, and proper nutrition can greatly increase the likelihood of reaching old age. Of course, this kind of research has helped improve the health of everyone along the way. Exercising and not smoking can have beneficial effects at any age. Similarly, proper nutrition can reduce the risk of diabetes, coronary heart disease, and stroke (OTA Report).

Additional research can provide new ways of promoting health in old age, thereby improving the quality of life and possibly reducing anticipated health care costs to society. Clearly, the payoffs that emerge from such research are widely distributed across generations.

Using the talents of the elderly serves the interests of the society as well as of the elderly. With more people projected to live longer, it seems likely that a significant portion of the future elderly may be both willing and able to work longer. Research being conducted today can provide the information needed--including developing ways to retain older workers beyond the normal retirement age--to assist employers and employees in adjusting to an aging work force.

In short, the research on aging done in response to the challenge of an aging society is an intergenerational transfer that will potentially play a large role in shaping the future, a transfer in which each generation, including the not yet born, have a common stake.

All Generations Benefit From Research on Aging

While current cohorts of the elderly often benefit directly from such research, indirect benefits also accrue to persons of all ages. For example, indirect benefits of research on aging may include decreased health care costs to taxpayers and reduced caregiving costs--financial, emotional, and physical--to families who provide support to older relatives.

Further, the actual benefits of most research on aging very often accrue to those who are not old. For instance, research on osteoporosis, a condition particularly noticeable among postmenopausal women, has resulted in a prescription for preventive maintainance involving diet (e.g., maintaining proper calcium intake), exercise to develop and maintain bone mass, and other life-style factors for women of all ages (OTA Report).

Indeed, research focused on a particular concern of an aging society may benefit only _future_ cohorts of the elderly. But although today's elderly and perhaps even today's middle-aged _may never benefit personally_ from some of this research, the knowledge that flows from their investments in research will be transferred as a legacy to future generations in society. In a very fundamental way, then, research on aging is an intergenerational transfer of great benefit to persons of all ages as well as to those yet to be born. It is an investment in our common future.

FY 1987 Administration Proposal and Its Impact

Funding for the National Institute on Aging, under the Administration's proposal, would be reduced from $156.5 million in FY 1986 to $145.8 million in FY 1987, a 7% reduction. In general, this would mean that no new initiatives, such as studying gender differences in aging, would be funded, and that all other programs would be continued but at reduced funding levels. For example, NIA could support only 145 competing research grants in FY 1987, as compared to 201 in FY 1986. In addition, funding would be reduced for the ten Alzheimer's Disease and Related Disorders centers, which conduct basic research on the disease as well as look at how to implement social supports and family care.

NIA's training program is slated for a 7.2% reduction in FY 1987, while the National Institute of Mental Health's clinical training program would be totally eliminated. Reducing the number of funded training positions severely threatens our ability to address the well-documented shortage of health and allied health professionals.

The Title IV program under the Older Americans Act would be severely reduced under the Administration proposal, which calls for a 50 percent funding reduction. This comes at a time when the Acting Commissioner of the Administration on Aging has made some positive attempts to reshape the Title IV program. For example, the Commissioner has developed an approach for continually assessing training needs within the field of aging. This type of baseline information is critical to setting realistic training goals and in determining how effectively these goals are being met.

GSA Funding Recommendations for FY 1987

In my comments, I have outlined the demographic trends and the new and multifaceted challenges they will present, particularly to you as members of Congress. Key decision makers such as yourselves will need up-to-date information to effectively chart and respond to an aging society.

In the past, Congress has demonstrated an understanding of the importance of gerontological/geriatric research and training through its support of the National Institute on Aging and the National Institute of Mental Health. These programs, as highlighted earlier, are beginning to make major advancements, and their potential for making significant contributions in the future is great. This momentum must not be slowed.

Recognizing the tight fiscal constraints facing Congress in FY 1987, the Gerontological Society strongly urges you to continue these programs at a minimum at current services levels. As I have attempted to emphasize in my remarks here today, an investment in these research and training programs may ultimately benefit us all through such indirect benefits such as decreased health care costs to taxpayers and reduced caregiving costs, as well as a healthier old age through improved health practices in earlier ages.

Senator PROXMIRE. Thank you very much. Halfway through your prepared testimony, you say that an estimated 1 in 5 persons aged 80 and over are having serious irreversible dementia, and the source is Franklin Williams. testimony in 1983.

Ms. SCHUTZ. Right.

Senator PROXMIRE. Then you go on to say 30 percent to 50 percent of patients in nursing homes have Alzheimer's disease.

Ms. SCHUTZ. Right.

Senator PROXMIRE. We have had recent testimony that Alzheimer's disease is not easy to diagnose, and that there is some question as to whether or not an individual has the disease.

Ms. SCHUTZ. It can't absolutely be diagnosed until the autopsy, although they have made great strides in doing that. I am sure Dr. Harman can address that more specifically as a scientist.

Senator PROXMIRE. He is our next witness.

Ms. SCHUTZ. Yes; but they have made great strides. it is true that that statistic isn't 100 percent accurate, that they cannot say that for absolute, but they are getting much more sophisticated in the diagnosis.

Senator PROXMIRE. So when you say that about 1 in 5 persons aged 80 and over have serious irreversible dementia, even though the research is fairly recent, 3 years old, there may have been more precise statistics produced since then. Is that the latest figure?

Ms. SCHUTZ. I don't have a figure later than that.

Senator PROXMIRE. Let me ask you this. At a time when the administration is trying to limit the amount going into research on Alzheimer's disease, to take one example, do you think we should continue to give funding attention to demography?

Ms. SCHUTZ. Yes; I agree with the gentleman who spoke earlier. It is a smaller amount of money, and it is absolutely essential to have accurate data. The research, without accurate data, is no good. If you don't have the demographics of what is going on, then you can't do the correct research. You are not going to match research to the needs if you don't have data.

Senator PROXMIRE. I think there is no question about maintaining the data base. The question is: Is research involved in demographics?

Ms. SCHUTZ. I don't know specifically what you are referring to. I would say that generally, you could say that research is demographics.

Senator PROXMIRE. He was talking about proceeding with the data base.

Ms. SCHUTZ. I think the demographics are constantly changing, so you can't stop conducting research in demographics, or you are not going to have, like I said, you are not going to have accurate information.

Senator PROXMIRE. How do the figures compare? You say there has been much less involved in demography research.

Ms. SCHUTZ. I'm sorry. I don't have that figure in front of me. I would be happy to get it and supply that.

Senator PROXMIRE. Will you do that for the record?

Ms. SCHUTZ. Certainly.

Senator PROXMIRE. Thank you for your excellent presentation.

Ms. SCHUTZ. Thank you.

STATEMENT OF DENHAM HARMAN, M.D., PH.D., EXECUTIVE DIRECTOR, AMERICAN AGING ASSOCIATION (NEBRASKA)

Senator PROXMIRE. Our last witness is Dr. Denham Harman, the executive director of the American Aging Association. You are a very patient man. We are delighted to have you.

Dr. HARMAN. Mr. Chairman, ladies and gentlemen, my name is Denham Harman. I am the executive director of the American Aging Association, Millard professor of biochemistry at the University of Nebraska College of Medicine in Omaha, NE. I appreciate the opportunity to speak before this committee in terms of basic biomedical research.

Life expectancy at birth can be divided into two parts: one, the functional lifespan, that is the span of healthy, productive, useful life; and two, the verbal period decline due to toxic and other disorders.

Life expectancy is now 74.8 years on an advance to a plateau figure of about 75 to 76 years. Future disease oriented biomedical research is not apt to increase this figure, but should increase functional lifespan somewhat. It is time to start deemphasizing the disease approach to increase the functional lifespan and to start emphasizing research directed to determine the cause of aging.

The aging process produces widespread change throughout the cells and tissues that are believed to be responsibe for ever-increasing susceptability to disease and death that accompanies advancing age. Future increases in functional lifespan decreases in this period, and possible increases in our maximum lifespan, which is about 100 years, will only be achieved by slowing and/or preventing the changes produced by the aging process.

Attempts can be made to do this. We have been shown promise. Reducing the caloric intake of mice and rats delay the onset of degenerative disease and significantly increase the lifespan. Similar action is obtained by a number of components such as vitamin E to the diet.

How the aging process produces changes observed with time is a matter of dispute. Many hypothesis abound. A concensus would be only to a major area. Only then can we expect to see clearly and prevent aging.

Many would say that this event should not be made. They point out that the burden placed on society by the older age group is already large and could get greater. Older aging would simply make the problem worse by increasing the number of older persons. They feel that efforts to increase the quality of life of the elderly should be limited to improving the present make-do approach by providing for better nursing homes, more services, and improved medical care. The projections are probably wrong.

A growing number of individuals are trying to increase their functional lifespan by diet—I see them all around the room—exercise and consumption of food supplements of vitamin E, vitamin D, and decreasing the terminal illnesses by living well.

In all probability, even in the abscence of efforts to slow the aging process, the elderly will be healthy in the future and require less support from society rather than more. The American Aging Association urges the NIA to initiate a major biomedical aging research program focused on determining the cause of aging and to apply that knowledge to increasing our span of a healthy life.

PREPARED STATEMENT

In summary, life expectancy at birth, now 74.8 years, is slowly reaching the plateau value of 75 to 76 years imposed by the aging process. Slowly this process should increase our healthy lifespan and diminish our problems associated with age. We urge the NIA to initiate a major biomedical aging research program directed to this end and that Congress ensure the necessary funds.

Thank you.

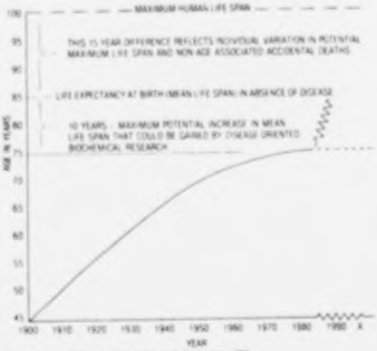
[The statement follows:]

STATEMENT OF DENHAM HARMAN

My name is Denham Harman, M.D., Ph.D. I am Executive Director of the American Aging Association (AGE), Millard Professor of Medicine and Professor of Biochemistry at the University of Nebraska College of Medicine in Omaha, Nebraska.

I appreciate the opportunity on behalf of the American Aging Association to amplify my oral testimony before the Labor-HHS-Education Appropriations Subcommittee of the United States Senate on the pressing need to support biomedical aging research.

Life expectancy at birth is the sum of the span of healthy productive life, i.e., the functional life span, and of the period of senescence. Life expectancy at birth in the United States rose rapidly from a value of 47.2 years in 1900 to 69.7 years in 1954-1955 and then progressively more slowly to the present value of 74.8 on an advance to a plateau figure of about 75-76 years as indicated in the figure below.



Average life expectancy at birth in the United States since 1900

Today life expectancy is about 10 years less than the maximum average life expectancy at birth of around 85 years, the value to be expected in the absence of overt disease. Thus "conquest" of cancer would extend life expectancy about 2 years, elimination of the cardiovascular diseases approximately 5 years, and of all the other disorders listed on death certificates about 3 years. Although further increases in average life expectancy from disease oriented biomedical research are not likely, such research should decrease somewhat the average period of senescence.

Biomedical aging research seeks to further increase the functional life span by identifying, and then preventing or slowing, the accumulation of those changes in our bodies with time responsible for the ever-increasing susceptibility to disease and death with advancing age. Age related changes are found in all the cells and tissues. They include changes in enzyme activities, formation of age pigment - insoluble material formed largely from unsaturated lipids, amyloid, stronger binding between collagen fibrils, decreased elasticity of the large blood vessles, senile plaques - focal areas of tissue degeneration in the brain, loss of cells in some areas of the brain, and decreases in the number of mitochondria - the place in our cells when the energy released by the 0_2 we utilize is converted to a useable form. Changes such as these, attributed to the aging process, collectively increase susceptibility to disease and death.

Preventing, or slowing, changes such as those listed above should decrease susceptibility to disease and death and increase our healthy life span. In doing so we will put off to a greater age the heart attacks, cancer, etc. that will kill us, as well as the other problems associated with age such as Alzheimer's disease and senile macular degeneration - a major cause of decreased vision in the elderly. Through slower aging, a man or woman in the future at age 60 may have the healthy and vitality of the average 45-50 year old of today.

The conviction that slower aging is a feasible possibility has been growing steadily over the past two decades, due to the gradual accumulation of knowledge of the effects of age on biological systems, and of reasonable hypotheses to account for such changes. For example, in studies based on one theory of aging, it has been easy to increase the average life span of mice by 20 percent (equivalent to increasing the life span of man from 75 years to 90 years) and to decrease the incidence of disease. Besides shifting the average life expectancy to higher levels, inhibition of the aging process may also increase the natural human maximum life span to some extent.

It is a reasonable possibility that investigation of the numerous hypothesis already advanced to account for the nature of the aging process, not to mention new ones that are likely to be suggested, will ultimately lead to an understanding of the nature of this process. Application of that knowledge should almost certainly increase our healthy life span, decrease the period of senescence, and thereby ameliorate the economic and social problems associated with age.

We spend several billions of dollars each year on research on cardiovascular disease and cancer, as well as for treatment of these and other diseases in order to increase our healthy life span. Prior to the establishment of the National Institute on Aging funding for aging research was negligible. Yet, aging per se is the process that has almost nullified all attempts to substantially increase our healthy life span for the past three decades. Even the current National Institute on Aging budget of around $150,000,000 is small when compared to our national yearly expenditure on major diseases. This is especially true since the National Institute on Aging funding figure also includes substantial support for non-biomedical programs.

It was the intent of Congress as expressed by Congressmen Tim L. Carter and Paul G. Rogers on page 275 of the House Congressional Record for May 6, 1974, that the National Institute on Aging should give emphasis to biomedical aging research, and in particular, to determine the cause of aging. Biomedical aging research is the only part of the umbrella mandate of NIA that is unique to the Institute, and by far the most important. The major intent of Congress has been largely ignored. Virtually no work is being done to slow the aging process because the vast majority of gerontologists are concerned with the "awesome social consequences of major breakthroughs in aging", as expressed by Robert Butler in his 1974 book "Why Survive? Being Old in America", and later, by Leonard Hayflick in the January 1982 issue of Executive Health, "At first though it may seem to be a desirable goal (to slow the rate of aging). I believe it might be an unmitigated disaster". Today essentially all biological, behavioral and social research studies on the aging process are descriptive in nature or related to support programs for older persons.

The concerns of the gerontologists are unwarrented. Life expectancy has increased 25 years since 1900 without producing any social upheavals. Future increases that may be achieved through slower aging are apt to be relativly small - 5 to 15 years, and long in coming - and will probably result in only a few more people living beyond 100 years, the "natural" maxium life span of man. Time, healthy useful time, is our most valued possession and makes all things possible. The benefits of having more such time to work, to contribute to society, and to do the other things we wish, vastly outweight any conceivable problems that might arise from slowing the biological process of aging.

The American Aging Association urges the NIA to initiate a major biomedial aging research program focussed on determining the biological basis of aging and to apply that knowledge to increasing our span of healthy life. The Salk vaccine became available 30 years ago, and stilled the clamor for more and better iron lungs. Likewise, slowing the aging process will surely decrease the demand on society for more services and better nursing homes for the aged.

The American Aging Association (AGE) was formed in 1970 in response to the pressing need for more biomedical aging research. AGE is a national lay-scientific health association pattered after the American Heart Association. A highlight of the American Aging Association's annual scientific meeting is the research symposium. A copy of the program for the 1985 meeting is attached.

To help further one of the basic goals of the American Aging Association, the organization has sponsored the formation of a new medical specialty, clinical gerontology. The inaugural luncheon of the American College of Clinical Gerontology was held on Friday, March 21, 1986 at the Waldorf-Astoria Hotel in New York City. Clinical gerontologists will utilize a combination of preventive medicine, geriatrics and clinically relevant biomedical aging. Individuals will be assessed at appropriate intervals throughout life. Initially, for recommendations regarding medications, diet, exercise, etc. - measures designed to slow the rate of aging and of disease processes. Later, for efforts to ameliorate the inevitable deleterious effects of aging and disease and to "cushion" the terminal period of life. These efforts should help each individual minimize the problems associated with age.

The first educational effort of the College will be a two-day series of clinical gerontology lectures. These will be presented in association with the 16th Annual Meeting of the American Aging Association, September 25-27, 1986, at the Capital Hilton Hotel in Washington, D. C.

In summary, life expectancy at birth, a rough measure of the span of healthy life, is now almost at a plateau value because of the aging process. Slowing this process should increase our healthy life span and diminish the problems associated with age. We urge the NIA to initiate a major biomedical aging research program directed to this end and that the Senate ensure the necessary funds.

Senator PROXMIRE. Thank you very much. Yours is a very fine statement to end on. It is upbeat to suggest that people can look forward to living a healthier, fuller, more fulfilling life as they get older instead of suffering all kinds of difficulties as they go through their seventies and eighties.

Dr. HARMON. I said some of these words to people. We could do a great deal more than we are doing. There should be more money for all the biomedical services.

Senator PROXMIRE. I understand 20 percent of the National Institute of Aging's budget is spent on nonbiomedical research involving the social and behavioral sciences. Do you think that is about the right ratio?

Dr. HARMAN. I have read the material they passed out at the 1981 White House conference. I would say it is excessive.

Senator PROXMIRE. You think it is excessive, that much money is too much?

Dr. HARMON. It is too much. I suggest you read it and see what we got for 20 percent of our money. Second, of the 80 percent which is left, that goes to biomedical research. It is a question of how you define research. I would say that very, very little of that money goes to the things I am talking about, basic biomedical research strictly to find what is the cause of aging and do something about it.

Senator PROXMIRE. Thank you very much. We very much appreciate your fine testimony.

Dr. HARMAN. I appreciate it.

ADDITIONAL SUBMITTED STATEMENTS

Senator PROXMIRE. The subcommittee record will remain open for any additional statements which may be submitted by individuals or organizations which could not testify today.

[The statements follow:]

STATEMENT OF THE ASSOCIATION FOR GERONTOLOGY IN HIGHER EDUCATION

Chairman Weicker and distinguished members of the sub-committee, this testimony is being submitted on behalf of the Association for Gerontology in Higher Education (AGHE). I am Elizabeth Douglass, the Association's Executive Director, and I ask that this testimony be accepted for the record. AGHE is a nonprofit membership organization of approximately 270 institutions of higher education that conduct research and provide education and training in the field of gerontology. This testimony will address the proposed FY 1987 budgets of the Administration on Aging's Title IV (OAA) programs, the National Institute on Aging, and the National Institute of Mental Health Center on Aging.

In a time of scarce resources, the temptation is strong for our country's political leaders to reduce funding for programs which do not evidence immediate payoff and to favor those programs which have a quick, visible, and dramatic impact on the society and the economy. Likewise, the expedient route is to relinquish altogether federal responsibility for some programs, adding them to the list of obligations for states and local jurisdictions.

We thank you for your support over the past several years and ask that you continue to be advocates for improving the lives of Americans of all ages through the continuation of the unique education, training, and research programs which the budgets of these three agencies fund. We appreciate your willingness to make an investment in the future and to reaffirm a federal responsibility for assuring the development of a research base and a supply of trained professionals in the field of aging.

Importance of Aging Education, Training, and Research. We argue that of equal value to service programs for older Americans are the (a) research activities which expand our knowledge about the aging process, (b) the demonstration projects which enable more appropriate and efficient service programs to be dessigned, (c) educational programs which prepare professionals to work in the field of aging, and (d) continuing education and training programs which upgrade the skills of persons already serving the elderly and their families.

Without these "supportive" programs the service delivery activities will most likely be ill-conceived and inappropriate and will be staffed by persons who do not understand the aging process, how to work effectively with older adults and their families, or how to be efficient administrators. The adage, "If you think education is expensive, try ignorance," is all too true. The waste of fiscal and human resources which occurs when planning is uninformed and personnel are untrained is an unfortunate reality. Private industry would never manufacture a product without the backing of research. The Defense Department would never operate the machinery of modern warfare without trained personnel. The health and social service arena is in no less need of a knowledge base and an educated and trained manpower.

You have already received testimony from the Gerontological Society of America on the large gaps in aging research which still exist and the need to prepare for an increasingly aging society by expanding our understanding of the aging process.

We are woefully behind as well in developing faculty and professionals for a "greying" society. Less than 10% of the medical schools in the U.S. require geriatrics as a part of their curricula. Less than 15% of the 1,400 basic professional education programs for nurses have specific courses in gerontological nursing. Less than 1% of masters and doctoral degree nursing graduates are in gerontology or geriatrics. The number of existing research faculty in our institutions of higher education is estimated by an NIA study to be about half of the need in the biomedical, behavioral, and social sciences. Only 15 % of the State Unit and Area Agency on Aging directors have received specialized training in gerontology. These are only a few examples of trained personnel shortages.

National Institute on Aging. The NIA was created in 1974 to conduct and support social, behavioral, and bio-medical research and training related to the aging process. Its program emphases include preventing and treating Alzheimer's disease and other forms of dementia, lengthening life expectancy, maintaining health and functioning in later years, nutritional studies, and clinical medicine. NIA's training programs have stessed discipline-based faculty training, particularly in the biomedical sciences. Its research programs tend to be basic rather than applied, with strong emphasis on clinical and biomedical research, addressing health issues of special relevance for older persons.

NIMH Center for Studies of the Mental Health of Aging. The Center on Aging, established in 1975, focuses on research, training and service related to the mental health needs of America's older population. Recent programs have concentrated on the causes, treatment, and prevention of Alzheimer's disease, senile dementia, and depression, psychopharmacology, alcohol and drug abuse, chronically mentally ill elderly, treatment intervention and service delivery models for the elderly. Training programs have focused on clinical psychologists, psychiatrists, psychiatric nurses, and social workers. It is the major source of support for training clinicians with primary responsibility for the care of mentally ill older persons.

Administration on Aging - Title IV. The Title IV research, training, and demonstration programs, begun in 1966, are the only federally-supported programs designed to support applied research for the social/behavioral needs of older adults; to train personnel in non-health professions to work with the elderly; and to develop demonstration projects to serve as community models for service delivery programs for older Americans. The major programs currently funded under Title IV are research and demonstrations, gerontology training (including career preparation), long term care gerontology centers, training and demonstrations for legal service programs for the elderly, and support to national minority aging organizations.

Examples of Currently Funded Projects. I would like to share with you information on three exemplary programs begun with AoA Title IV support which illustrate the wise investment of federal dollars in the long-range improvement of educational, research, and service delivery institutions.

(1) Enhancing the Quality of Gerontology Instruction is a survey research project being conducted this year by this Association in conjunction with the Andrus Gerontology Center at the University of Southern California. It is designed to determine the extent and character of gerontology instruction in America's colleges and universities. It is the first attempt in ten years to conduct a national survey of gerontology programs, and it is the first time ever that a survey of this depth and scope has been undertaken. The investigation will provide information on courses taught in aging, numbers and characteristics of gerontology faculty, numbers of past

and present gerontology students, funding sources for these programs, administrative structures, academic credentials offered in gerontology, relationships to traditional academic disciplines within the institution. The data base which this project will produce will have a broad and far-reaching impact on the future development of the field. It will enable informed planning to occur and appropriate targeting of limited resources.

(2) The National Data Base on Aging is a project initiated by the National Association of State Units on Aging (NASUA) and the National Association of Area Agencies on Aging (NAAAA) with funds from Title IV (OAA). It is a comprehensive, up-to-date information system dealing with statistics about the elderly and the services provided by the network on aging. Detailed information on the budgets, staffing, clients and services of State Units and Area Agencies on Aging are compiled. These service programs which operate in every county in the country include in-home care, nutrition, transportation, and other activities that promote independence. The data base is updated annually and encompasses a wide range of data from numbers and characteristics of persons served, to units and costs of service provided.

(3) The Hispanic Gerontology Internship Program is designed to provide on-the-job and in-service training for Hispanics by placing them in full-time administratively responsible positions in public and private aging networks. The project is sponsored by the Asociacion Nacional Pro Personas Mayores and is funded for one year by the Adminstration on Aging. Subsequent program years are pending funding. Interns receive a taxable salary and fringe benefits during their six months internship. Participation in the program provides training for qualified individuals to assume administrative/management positions within the aging network. A manual which promotes training and involvement of Hispanics as professionals in the field of aging will soon be available.

Administration's FY 1987 Budget Proposals and Their Impact. Not only have there been across-the-board 4.3% budget reductions in 1986 imposed by the Gramm-Rudman-Hollings Deficit Reduction Act, but there are dramatic reductions proposed by the Administration for the FY 1987 budgets of these three agencies.

NIA - The FY 1986 budget for NIA was $156.5 million; the proposed FY 1986 budget is $145.8 million. This proposed 7% reduction for NIA in general would mean that no new initiatives would be funded, and that all other programs would be continued but at reduced funding levels. NIA could support only 145 competing research grants in FY 1987 as compared to 201 in FY 1986. This would bring the number of supported research grants back to 1984 levels, and the size of the awards would be reduced significantly as well. One hundred ninety-five full-time training positions could be funded under the Administration's proposals in FY 1987, as compared to 240 in FY 1986.

NIMH - The FY 1987 proposed appropriation for NIMH is $242.4 million, compared to $309.2 million in FY 1986--a drop of 21%. Although there is no line item in the Administration's budget for the Center on Aging, it is assumed that the Center's budget would experience reductions similar to those proposed for the overall Institute. The most severe cuts are targeted toward the clinical training and demonstrations programs, which would be totally eliminated under the administration's budget. In FY 1986, 319 research grants were funded. Fifty-two of those will be dropped through Gramm-Rudman; another 10 would be dropped in FY 1987, lowering the total to 257. The research training program, the small grants program, and the research scientist program would all be significantly reduced.

AoA - Title IV. Title IV was funded at $25 million in FY 1986. The Administration is requesting $12.5 million for FY 1987. Between 1980 and 1986 support for Title IV has been reduced by 54%, by far the greatest reduction of any OAA program. A further cut of 50% in 1987, as proposed, would decimate Title IV. This would represent a 77% reduction since 1980. There is no guarantee that the Administration would continue to fund current Title IV programs under a much smaller budget, equitably cutting all by 50%. Assuming the cuts would be across-the-board, there would be about 43 research and demonstration grants (instead of 86), 16 gerontology training grants (instead of 32). The two remaining Long Term Care Gerontology Centers would probably be de-funded entirely. The other OAA programs have been frozen at FY 1986 levels in the FY 1987 budget; only Title IV is slated for a reduction.

Recommendations for FY 1987. A Congressional approval of the proposed FY 1987 cuts in these programs would further weaken this nation's faltering investment in the future of our society as provided through its education and research programs. While recognizing the serious economic constraints under which this committee is operating, this Association strongly urges that the budgets of NIA, NIMH, and the AoA at a minimum at current services levels. In particular we urge that Title IV (OAA) be funded at $25 million for FY 1987.

STATEMENT OF THE AMERICAN ASSOCIATION OF HOMES FOR THE AGING

The American Association of Homes for the Aging (AAHA) appreciates this opportunity to express support for maintaining adequate levels of funding in fiscal year 1987 appropriations for Older Americans Act programs and for the research, education, and training programs conducted and supported by the National Institute on Aging (NIA), and the National Institute on Mental Health, Center on Aging (NIMH).

AAHA is a national nonprofit organization representing approximately 2,800 nonprofit facilities which provide housing, health care, long term care, and community services daily to more than 500,000 elderly individuals throughout the United States.

Older Americans Act Programs

Since its enactment in 1965, the Older Americans Act has played an important role in helping to meet the social service needs of the elderly, as well as research and training demands related to the aging process. The success of Title III programs in providing congregate and home-delivered meals and other supportive services is undisputed. The Act's nursing home ombudsman program has been important in helping to protect and enhance the rights of nursing home residents. In addition, Title IV of the Act has made strides in aging research and in the training of professionals who serve the elderly.

AAHA urges the Subcommittee to maintain at least current year funding levels for Older American Act programs. Several factors are currently operating which make current support essential. First, the demographics of aging make it clear that there is an increasing elderly population in need of services provided by the Act. Each year, half a million Americans join the age 65 and over group, with the 75+ segment of the older population growing the fastest. These, of course, are the people most likely to require the kind of supportive services offered under the Act.

Second, much attention has been focused on the impact of the Medicare hospital DRG prospective payment system on the post-hospital long term care needs of the elderly. With a hospital reimbursement system that provides an incentive for earlier discharge of Medicare beneficiaries, needed access by the elderly to post-hospital Medicare skilled nursing home and home health care services has been highlighted appropriately by several Congressional committees. But as starkly illustrated by the extremely limited nature of Medicare post-hospital benefits, a large portion of the elderly discharged from hospitals are returning home more frail, technically ineligible for Medicare covered services but in need of supportive services which are provided by Title III programs such as meals, personal care services, and adult day care. At a time when the elderly's level of care needs are increasing, as well as the sheer number of older persons, reduction in funding for Older Americans Act programs are clearly unwarranted and would have an adverse effect on the elderly who are now able to benefit from these services.

Third, there is likely to be an increasing demand on Older Americans Act programs to address the supportive needs of the elderly residing at home as other federal programs such as the community services block grant, low-income weatherization, and revenue sharing are targeted for major reductions or elimination by the Administration.

The Administration has proposed that Title III be funded at $669 million. While characterized by the Administration as an increase in funding over fiscal year 1986, (fiscal year 1986 funding has suffered a Gramm-Rudman reduction), this amount really represents merely a return to the level of funding provided in fiscal year 1985. Obviously, $669 million for Title III in fiscal year 1987 does not account for inflation, albeit smaller than in previous years, or for the increasing numbers of elderly in need of services. Given current pressure to reduce the federal deficit, however, AAHA supports the $669 million funding level as the minimal amount necessary to support Title III programs in fiscal year 1987.

The Association also urges the Subcommittee to reject the Administration's request for cuts in funding for Title IV programs and to appropriate at least $25 million, for these activities in fiscal year 1987 -- the pre-Gramm-Rudman fiscal year 1986 funding level.

Aging Research and Training: National Institute on Aging (NIA) and National Institute on Mental Health, Center on Aging (NIMH)

The Association is also extremely concerned over the Administration's proposed fiscal year 1987 cuts in funding for the National Institute on Aging (NIA) and the National Institute on Mental Health, Center on Aging (NIMH) which are being aggravated by the fiscal year 1986 reductions imposed by the Gramm-Rudman-Hollings Deficit Reduction Act. The need for continued research and research-related training into the aging process and the concomitant study of disorders occurring among the elderly is one strongly supported by AAHA. The subsequent translation of this research into improved diagnostic, treatment and management techniques is embodied in the commitment of AAHA members to the provision of the highest quality of care to these individuals.

National Insitute on Aging (NIA)

The NIA, through a series of intramural and extramural research programs and initiatives, has undertaken gerontological studies and projects on a variety of medical and psycho-social levels. Representative areas of research include the effects of aging on the immune system, the brain and nervous system, intellectual functioning, and personality and behavioral changes, as well as changes in response to various drugs and medications with increased age. NIA has also conducted several years of research related to the prevention and treatment of Alzeheimer's Disease.

Since 1984, ten multidisciplinary Alzheimer's Disease Research Centers have been established through funding granted to NIA. AAHA commends the creation of these centers and the Institute's commitment to the advancement of research into the cause, prevention, and treatment of Alzheimer's Disease. The Association has also identified this as a priority issue and has developed a member network on Alzheimer's Disease to provide a central vehicle for the sharing of information and resources. Most recently, an AAHA member task force has been appointed to work with the Association on determining how it can best serve the needs of AAHA members caring for Alzheimer's patients.

There are currently 2.5 million Americans suffering from Alzheimer's Disease, a degenerative condition, often progressing over a period of seven to twelve years, which results in loss of memory and judgement, agitation, and confusion. As the disease advances there is an increasing need for constant supervision and surveillance. This places an extremely heavy burden on family caregivers who, as in the cases of spouses, are frequently elderly themselves. The availability of home support services is expanding; however, nursing home placement is almost always required as the Alzheimer's victim's need for health related services and direct care extends beyond the caregiver's capacities. Due to the high degree of involvement required by staff in direct care behaviors, institutional management of the disease is also labor intensive.

The presence of Alzheimer's Disease can only currently be determined with absolute certainty through performance of an autopsy. Although exhibiting symptoms related to Alzheimer's, individuals may, in fact, be suffering from conditions whose causes are treatable and possibly reversible. Continued research into the development of a comprehensive assessment and diagnostic tool to identify year Alzheimer's Disease is essential to providing appropriate responses to the needs of its victims and to the timely and effective treatment of other conditions which may be masked by the presence of Alzheimer's symptoms. The cost of treating and maintaining Alzheimer's patients is huge in terms of both dollars, amounting to more than an estimated $20 billion annually in nursing home care, and in the vast amounts of time and skill invested by the broad range of health care professionals who are involved. AAHA urges not only the continued and full funding of the ten existing Alzheimer's Research Centers, but, also advocates the extension of this program as proposed in the Comprehensive Alzheimer's Assistance, Research, and Education Act of 1985 (H.R. 2280), introduced by the Representative Edward R. Roybal.

National Institute on Mental Health, Center on Aging (NIMH)

The NIMH, Center on Aging, focuses on research, training, and services related to the mental health needs of the elderly. It is the major source of support for training clinicians specializing in the care of geriatric populations. NIMH has also recently concentrated on research related to Alzheimer's Disease, as well as on the study of Senile Dementia and depression, psychopharmacology and the chronically mentally ill elderly. One extremely important aspect of the training and research conducted by NIMH is the development of treatment intervention techniques and service delivery models involving clinical psychologists, psychiatrists, psychiatric nurses, and social workers.

The Administration's proposed budget reduction of 7 percent for fiscal year 1987 coupled with the effects of inflation would mean no new initiatives for NIA and reduced funding levels for all existing programs. The budget proposal would reduce monies for research project grants by $9.6 million, bringing the number of supported research grants back to 1984 levels. (This does not take into account the effects imposed by Gramm-Rudman-Hollings or proposed rescissions). NIA would be forced not only to support fewer research grants, but, to lower award amounts. Although the reduced funding levels proposed for NIMH, 21 percent from fiscal year 1986 to fiscal year 1987, are not specific to the Center on Aging, the most severe reductions which have been targeted for this Institute are directed toward the clinical training and demonstrations programs. These programs would be totally eliminated under the Administration's proposals.

AAHA strongly supports the continued funding of these programs and the subsequent dissemination of information as vital to ongoing advances in the care of the aging in both institutional and non-institutional settings.

The number of individuals over 65 years of age, currently numbering 28 million, is the fastest growing segment of the U.S. population. According to the Bureau of Census, by the year 2050, one in eight Americans will be at least 75 years old. Our ability to provide services necessary to ensuring the highest quality of life to this population can only be enhanced through the continued funding and implementation of research, training, and education programs.

Again, AAHA thanks the Subcommittee for this opportunity to express its views and urges the Subcommittee to appropriate sufficient funds for fiscal year 1987 at least to maintain the pre-Gramm-Rudman level of commitment to these important aging services and research programs.

STATEMENT OF D. KAY CLAWSON, M.D., EXECUTIVE VICE CHANCELLOR, UNIVERSITY OF KANSAS MEDICAL CENTER

I'm writing in support of the National Institute on Aging's budget request. As Executive Vice Chancellor of the University of Kansas Medical Center, I am the Senior Medical Administrator over the health programs at the University of Kansas, which comprises, the School of Medicine, admitting 200 students annually, Schools of Nursing and Allied Health with a total student body of 2,500 and a budget in excess of $180 million.

The University of Kansas, the Kansas Board of Regents and the Kansas Legislature have recognized aging as one of the major concerns of the citizens of Kansas. Four years ago, our state legislature authorized the hiring of a trained geriatrician and one year ago, reinforced its commitment by appropriating funds to develop a Center on Aging to bring together a multi-disciplinary approach to research, education, and patient care. Our institution has conducted nationwide searches on two occasions, and have failed to attract academically qualified geriatricians suitable for this position. We can speak from this personal experience of the severe shortage of qualified individuals in the field.

Regrettably, our experience is not unique, but is similar to that of many other institutions, all now engaged in a competition for the few well-trained academic gerontologists in this country. Therefore, we urge full funding support for enhanced training and career development in geriatrics and gerontology under the National Institutes on Aging; particularly support for geriatric leadership academic awards and complimentary training awards for research on aging. Without a cadre of well-trained academicians, the physicians and health professionals being educated today will not be sufficiently knowledgeable about the unique health care needs of the aging patient. In particular, we need physicians who are knowledgeable in the prevention of the deterioration with aging through preventive measures and high-tech care.

Again, I urge full support for what I believe to be the nation's number one health and social problem for the 21st century. As we anticipate major growth in the number of indivuduals who will survive into their 70's, 80's and 90's, I particularly want to stress the need for full funding for the training programs necessary to develop a cadre of academicians to teach the principles of gerontology to our future generations of health professionals.

STATEMENT OF THE AMERICAN ACADEMY OF DERMATOLOGY, INC.

Mr. Chairman, I am Peyton E. Weary, M.D., Professor and Chairman of the Department of Dermatology at the University of Virginia School of Medicine and Washington Representative from the Council on Governmental Liaison of the American Academy of Dermatology. I am also the immediate past Vice-President of the Society for Investigative Dermatology. I am presenting this testimony on behalf of the American Academy of Dermatology, whose membership of over

6,500 represents the majority of American Dermatologists, and on behalf of The Society for Investigative Dermatology, the representative organization for the dermatologic biomedical research community.

I am delighted that, after more than ten years of testifying before this Subcommittee, I have the honor, this year, to testify in support of a new institute, The National Institute of Arthritis and Musculoskeletal and Skin Diseases which represents the culmination of a dream for many of us. We applaud the determination of the Congress to create this new institute in recognition of the contribution of a large number of disabling and disfiguring chronic diseases to the burden of illness in our society. In calculating the socioeconomic impact of these diseases, it is important to bear in mind that it is estimated that approximately 60 million Americans will have a significant skin disease during their lifetime and the estimated annual combined direct and indirect cost of skin disease is 6.8 billion dollars. The challenge now for all of us is to make this new institute the best and most productive it can be and the dermatologic organizations pledge our support for this effort.

Mr. Chairman, we feel it is essential in any new venture to assure that the financial base is adequate and secure and, it is for this reason, that our organizations support the recommendations for funding in the amount of $151,650,000 prepared by the coalition of organizations concerned with programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases for FY 1987. We believe that scientific opportunities are clearly identified which would justify the level of support suggested. You will note that the coalition's recommendations call for additional funds in the amount of 2.4 million dollars to support six core centers in dermatology and we strongly endorse this new initiative in the belief that it will provide significant new opportunities to capitalize upon the recent advances being made in a number of important areas of dermatologic research. Among the frontier areas of dermatologic research, I would direct your attention particularly to the following:

1. There are significant new advances in understanding several of the blistering diseases such as Epidermolysis Bullosa and Pemphigus as outlined for you earlier by Dr. Shulman in his testimony.

2. The use of cultured skin cells as a mechanism for grafting burns, ulcers and denuded skin suggests exciting new horizons for research.
3. A family of compounds derived from Vitamin A called retinoids has revolutionized the treatment for severe acne and holds great promise for a number of other disabling diseases such as psoriasis.
4. The discipline of photobiology which studies the effects of visible light and ultraviolet radiation upon the skin is expanding rapidly, and ultraviolet light is even being used on an experimental basis by dermatologists to kill malignant cells in the blood through a process called photophoresis.
5. There are inherited disorders in which the horny layer of the skin thickens and which are called, as a group, ichthyosis. As science continues to unlock basic aspects of disease more and more of such inveterate diseases yield to new therapeutic efforts.

I would emphasize that these are only some of the exciting new opportunities which have been generated by previous NIH support and await your continued support through the provision of adequate funds for the research activities in the new institute.

Mr. Chairman, we support the recommendations for overall N.I.H. support of the Ad Hoc coalition for biomedical research. We also wish to express our continuing concern about funding levels for several other institutes at the NIH (NCI, NIA, NIAID, NIEHS) and for the National Institute for Occupational Safety and Health. All of these institutes support important research in skin disease and, in particular, we direct your attention to the superb intramural program in dermatology research which is located in the NCI. With the increased incidence of skin cancer and, in particular, malignant melanoma, support of research on cancer of the skin is most appropriate. This research provides an important adjunct to the efforts of dermatologists to detect and prevent skin cancer and, in particular, malignant melanoma through the more than 400 skin cancer detection and prevention clinics held last year. This year our efforts at skin cancer detection and prevention will be expanded and targeted particularly to elderly Americans.

We continue to have concern about the levels of funding for the National Institute for Occupational Safety and Health. Previous funds are not adequate to support much needed research in occupational skin disease which causes such a significant economic loss to this country's productivity.

Thank you for the opportunity to express our views and also our appreciation to the Congress for their continued support of the NIH. Next year the NIH will have its centennial celebration. I for one believe this should represent a celebration of a most enduring and rewarding partnership between the NIH, the Congress and the administration, for without each of these three working for the advancement of medical science, the preeminence of the NIH would not have been possible. So we applaud you for your role in this partnership and hope for your continuing leadership in improving the health care of the nation through research.

STATEMENT OF THE AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS AND CONGRESS OF NEUROLOGICAL SURGEONS

Mr. Chairman and members of the Committee, thank you for the opportunity to appear here today to discuss funding for the National Institutes of Health and more particularly for the National Institute of Neurological, Communicative Disorders, and Stroke.

I am W. Kemp Clark, M.D., Professor of Neurosurgery at the University of Texas, Health Science Center in Dallas. I speak for the American Association of Neurological Surgeons and the Congress of Neurological Surgeons, who represent more than 2900 neurosurgeons in the United States.

Organized neurosurgery's primary concern is the stability of research support from the National Institutes of Health. We note, with great concern, the atmosphere of uncertainty the President's recent budgets have created in the research community. We were under the impression that last year the Congress and the Executive Branch had reached a mutually acceptable level of support for competing awards only to read that the recommended level of competing grants for FY 1987 is 5,104 or nearly a 1,000 less than in FY 1986 HHS appropriations signed by the President. The National Institutes of Health, in our view needs to have a reasonable idea of what the future holds for funding in order to effectively carry out its programs. We therefore recommend that you consider providing monies in FY 1987 for competing grants at the FY 1985 level of 6219.

We also want to address the issue of laboratories and equipment. From our experience we believe that there is a real need for the Congress to enact a plan for the modernization and updating of existing research facilities and equipment. While there is presently some ongoing modernization of our National facilities, I fear that it is rather piecemeal and often only done when a few extra dollars are available and without a well developed plan. We therefore propose that a specific five year plan be developed and funded to renovate outmoded research laboratories and equipment both for the Intramural and Extramural programs at the National Institutes of Health. Unfortunately, Mr. Chairman, we do not have the expertise to offer specific guidelines on the dollar amounts for such an effort for all disciplines. We are prepared to share our specific observations about the needs of the neurosciences.

I am pleased to report to the Committee that the support of the Federal Government at the National Institutes of Health and the Veterans Administration has been very helpful in neurotissue implantation and clinical research in the epidemiology, occupational hazard, economic cost, and treatment efficacy in low back pain.

Research continues, in an exciting way, in those neurologic diseases which may prove to be due to deficiencies in neurotransmittors, as has been shown in Parkinson's Disease. It may be true in Alzheimer's Disease as well.

In order to continue these and other efforts in the multifaceted mission of the NINCDS, we propose a moderate increase in research support. For example, in order to fund the NINCDS programs at a 40% funding rate the following support levels will be necessary:

	1987 Needs at 40% Funding Rate	
	Number	Dollars
1. Research Grants		
A. Projects		
1. Non-Competing	1,356	$229.547
2. Competing	956	162.434
Subtotal Projects	2,312	$396.981
B. Research Centers	44	$ 35,000
C. Other Research	330	19,900
Total Research Grants	2,686	$451,881
2. Training Programs		
A. Individual Awards	253	$ 5,486
B. Institutional Awards	384	7,979
Total Training	637	13,465
3. R & D Contracts	70	$ 14,250
4. Intramural Research		54,450
5. NINCDS Program Direction		19,600
TOTAL		$553,646

Thank you for your time and interest. I want you to know that Neurosurgery in America is grateful for your historic interest in a strong NIH research program.

SUBCOMMITTEE RECESS

Senator PROXMIRE. The subcommittee will stand in recess until 9:30 a.m. on Tuesday, May 6, when we will meet in SD–116 to continue our hearings on public witnesses.

[Whereupon, at 12:14 p.m., Thursday, May 1, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, May 6.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

TUESDAY, MAY 6, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:40 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Specter, Proxmire, Burdick, and Inouye.

NONDEPARTMENTAL WITNESSES

Senator Weicker. The committee will come to order. This morning will continue our public witness hearings on the Department of Health and Human Services, to include general testimony on the National Institutes of Health [NIH] and the Health Resources and Services Administration [HRSA].

I would appreciate it if everybody would observe the 4- to 5-minute time limit, as imposed by these lights, as a courtesy to your fellow witnesses. We have a long list. It would be appreciated if you could accommodate them.

If all of a sudden I have to jump out of this chair, I hope you will forgive me. Having four children under the age of eight, I am not immune to the things that occur to parents. I feel like hell today. I figure you would rather have me out of the room than in the room.

Under those circumstances, we will start off with our lead witness, Dr. Robert Petersdorf, the president-designate, Association of American Medical Colleges [AAMC]. Dr. Petersdorf?

STATEMENT OF ROBERT G. PETERSDORF, M.D., PRESIDENT-DESIGNATE, ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Dr. PETERSDORF. Good morning, Mr. Chairman. My name is Robert Petersdorf. I am currently the vice chancellor for health sciences and dean of the University of California, San Diego School of Medicine, and in September, I will become the new president of the Association of American Medical Colleges.

I am honored to present the views of the association before this subcommittee.

At our association's annual meeting last November, your eloquent remarks struck a very resident chord, so that our constituencies for the first time in memory tended to speak a well deserved ovation. I would like to reiterate our deep appreciation for your articulate and effective commitment to scientific research, education, and health care.

Our message today is quite simple. The Federal Government must follow the policies that continued investment in research and education is an investment in our country's future. This policy should remain steadfast whatever the vagaries in the economy. Somehow, we must find the money to keep America's unparalleled research and education enterprise alive and responsive for the steadily increasing momentum of discovery in the sciences.

I can only highlight a few items for the fiscal year 1987 appropriations bill. More detail is included in the longer statement that I hope you will include in the record.

In just the short span of my own career in medicine, there has been phenomenal growth in our power to deal with disease, a power directly traceable to the new knowledge that has accrued from wise past investments. Despite this new knowledge and the clear cut results that spent from it, many intractable problems remain that have flaunted medicine's effort to combat disease and disability and premature death.

In our view, the only hopeful solution of these unsolved problems is through the steady funding of the best and most innovative research, whether the times be good or bad. Research must be constantly nurtured by training the brightest young applicant scientist by providing state-of-the-art facilities and equipment and by supplying the other necessary resources to make research successful.

The ad hoc group for medical research funding comprised of over 150 organizations of which the AAMC is one, has recommended that just over $6 billion be appropriated for the NIH and $465 million for the Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA] research and training in fiscal year 1987, to provide modest real growth in these agencies and to remain responsive to the scientific needs.

In the area of student assistance, the AAMC believes that financial aid is also an investment in America's future with benefits far exceeding the costs. The AAMC has long held that students and/or their families should strive to pay for their own education, however few these days can shoulder this burden out of pocket and most are forced to borrow. Many, particularly those from socioeconomically disadvantaged backgrounds, are not even applying for medical school because of the spectra of insurmountable debt upon graduation.

It has been argued that the increasing adequacy of physician supply should relegate health professions educational assistance to a lower priority. We disagree with this. Even if medical school classes were cut in half to curtail physician supply, Federal scholarships and subsidized loans would still be critically needed so that the most worthy candidates could attend medical school regardless of their ability to pay.

The title VII health professions training programs do not produce more doctors but doctors more responsive and attuned to national needs.

For these reasons, the AAMC urges a current services budget for the student assistance and health manpower education programs under title VII.

Mr. Chairman, I have laid before you what the AAMC perceives as vital national needs. Meeting these needs should be viewed as an investment in America's future, since today's down payments will yield untold benefits tomorrow.

PREPARED STATEMENT

We appreciate your dedication to these goals and trust that you will continue your wise assistance in the overarching importance of research and education. Thank you for the opportunity to present these views. I would be happy to answer any questions.

[The statement follows:]

STATEMENT OF ROBERT G. PETERSDORF

The Association of American Medical Colleges (AAMC) appreciates this opportunity to submit its views on FY 1987 appropriations for the Department of Health and Human Services and the Department of Education. The Association represents the whole complex of individual organizations and institutions charged with the undergraduate and graduate education of physicians. It serves as the national voice for 127 accredited medical schools and their students; 435 major teaching hospitals and over 80 academic and professional societies whose members are engaged in teaching, biomedical and behavioral research, and patient care. All of these activities are directly affected by programs under the jurisdication of the Labor-HHS-Education Appropriations Subcommittee. Exemplarily, almost 52 percent of the extramural investments of the NIH are in AAMC-constituent institutions.

Our message to this Subcommittee is quite simple: the federal government must be committed to the policies that continued investment in research and education is an investment in our country's future, and that our nation's poor and elderly should have access to quality health care, regardless of their ability to pay. These commitments should remain invariant, whatever the periodic and episodic fluctuations in the economy, lest short-term decisions driven by today's fiscal constraints have severe scientific, economic and societal repercussions tomorrow. Somehow, money must be found to keep America's unparalleled research and education enterprise alive and responsive to the steadily increasing momentum of discovery in the biological, behavioral and medical sciences, and to ensure that all citizens are able to obtain medical care.

The past four decades have witnessed a virtual revolution in the power of physicians to deal with the many diseases that afflict mankind, a power that is directly traceable to knowledge accrued from wise past investments that are paying off today. However, despite our new knowledge-based power, many intractable areas remain where nature presents medicine with tremendous challenges in its efforts to combat disease and disability. This country can and must meet the challenges posed by the 2 million elderly Americans afflicted with Alzheimer's disease; the 1 out of 3 babies destined to develop cancer in their lifetimes; the 60 million Americans with cardiovascular disease; the 3.5 million stroke victims; the 2 million children with mental disabilities so severe that they require constant care and attention; and countless other people with diseases too numerous to mention.

The Association believes that the only hope of meeting these challenges is through the steady funding of the best and most innovative research. By its very nature, research cannot be turned on and off; it must be constantly nurtured by taking on the brightest young scientists, providing state-of-the-art facilities and equipment, and supplying the necessary funding to make it all work. In this enterprise, the federal government plays a unique and vital role---by supporting the two federal crown jewels of research, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA). The ripple effects of continued investment in basic research conducted at these agencies are felt in many sectors of the economy, as advances developed through such research nurture the burgeoning biotechnology industry, help to reduce health care costs and contribute to deficit reduction. A strong research enterprise also positively affects employment, the foreign trade balance and industrial development.

The President's proposed FY 1987 funding levels for the NIH and ADAMHA are shocking. If enacted, the ability of these agencies to maintain America's preeminence in research would be seriously compromised and the hopes of millions of Americans who anxiously await new discoveries in biomedical and behavioral research would be dashed. At a time when funding should be increased to meet the increasing costs and complexities of conducting modern research, the Administration has proposed only $4.9 billion for NIH and $337 million for ADAMHA research and training in FY 1987, a substantial decrease (8 and 13 percent respectively) from the thoughtful and responsible levels appropriated by this Subcommittee for FY 1986.

Consider the impact of the President's budget on these research programs. The NIH's award rate for competing research project grants would fall from 37.2 percent in 1986 to a dismal 27.4 percent of approved applications, thereby signaling a substantial Federal retreat from support for research. Not only would these drastic reductions thwart the pursuit of new opportunities in the health sciences, but would seriously decrease the attractiveness of careers in health research. Many well-trained investigators with innovative ideas will be forced out of the research field and many bright young students will surely be discouraged from entering it, causing the pace of discovery in the coming years to slow measurably.

The Ad Hoc Group for Medical Research Funding, a coalition of over 150 organizations---including the AAMC---whose members are engaged in biomedical and behavioral research, has recommended that the NIH be funded at $6.078 billion and that the research and training programs of ADAMHA be funded at $465 million in FY 1987. The Association strongly supports these levels that would provide only very modest program growth over a current services level. The Association has heard no complaints that these recommendations are too high, and many that they are not high enough; nevertheless, they seem minimally responsive to scientific needs given the current economic climate.

The Ad Hoc Group's recommended levels would allow competing and noncompeting research project grants to be funded at study-section recommended levels, with a priority score cut-off of approximately 170 and an award rate close to 33 percent at NIH; comparable parameters at ADAMHA would be 175 and 48 percent, respectively. Even at these funding levels, however, over 12,000 worthwhile research grant applications at NIH would be unfundable. The Ad Hoc Group's recommendation would also: fund about 11,500 research trainees at NIH and 1,200 at ADAMHA, as recommended by the National Academy of Sciences; enable modest renovation and upgrading of outmoded and inefficient research laboratories in the seven national primate centers; stabilize funding for research centers to facilitate the conduct of clinical research projects and clinical trials; and maintain other essential programs at FY 1986 appropriations levels.

These recommendations reflect a concern with flexibility and program balance. The management of NIH and ADAMHA need budgetary flexibility and freedom to use their discretion if scarce federal research funds are to derive the "biggest bang for the buck." Determination of the optimal balance among investments in the conduct of basic and applied research, the training of qualified investigators, and the application of knowledge gained from these activities to the public is complex, highly technical and strongly influenced by the precise state-of-the-art in the program purview of each institute. The professional managers of the several national institutes with their extensive scientific advisory apparatus are in the best position to do this, provided sufficient flexibility is available to them.

In the area of student assistance, the AAMC has a long-held philosophy that students and/or their families should bear the primary responsibility for paying for their own educations. Realistically, however, few students or families can shoulder this burden out-of-pocket anymore, and most are forced to borrow up to 75 percent of their medical education costs. Indeed, many qualified college graduates, particularly those from socio-economically disadvantaged backgrounds, are not even applying to medical school because of the specter of insurmountable debt upon graduation. By 1985, the percentage of indebted students had risen to 87 percent with average indebtedness of $30,000. Even the Guaranteed Student Loan Program, which has been the cornerstone of medical school financing, has not kept pace with inflation. Although GSL loans have decreased by 25 percent in real terms since 1976, inflation-adjusted medical school tuitions since that time have literally skyrocketed by 113 percent for private schools and 95 percent for public schools.

As a matter of principle, schools of medicine strive to accept the most worthy candidates who apply for admission, regardless of their ability to pay. As a result, medical schools have increasingly sought to expand their own resources for student financial assistance, and the access of their applicants and enrollees to other aid sources. Medical school endowments now provide well over 10 percent of all student financial assistance, a large but still insufficient amount relative to the increasing costs of medical education.

In 1963, when the federal government adopted the public policy of increasing medical school enrollment to address the physician shortage, it promoted equality of access to medical education by providing scholarships, loans and loan guarantees. The Reagan Administration, however, has continuously argued that the increasing adequacy of the physician supply should relegate health professions educational assistance to a lower priority. The Association strongly disagrees with this policy: even if medical school classes were cut in half to curtail physician supply, federal scholarships and subsidized loans would still be critically needed to ensure that the most worthy applicants could matriculate, irrespective of their economic status.

The Association firmly believes that health professions training programs funded under Title VII of the Public Health Service Act do not produce more doctors, but doctors more responsive and attuned to national needs. These programs, which include Health Education Assistance Loans (HEAL), Health Professions Student Loans (HPSL), Exceptional Financial Need Scholarships (EFNS) and the National Health Service Corps (NHSC), promote greater access to medical education, encourage physicians to practice in underserved areas, and emphasize such national priorities as primary care, geriatrics and cost efficiency in the delivery of health care.

The Administration, however, has proposed major reductions in, or outright elimination of, many of these programs in FY 1987. The AAMC believes that at least a current services budget for health manpower and student assistance programs is necessary for FY 1987. We would also urge that the entire $290 million in HEAL credit authority for FY 1987 be made available to students, particularly since HEALs accounted for 18 percent of all medical school financing in the 1984-1985 academic year. We also recommend that the HPSL program, which has received no appropriation for the past 3 years be provided full funding. HPSL remains an extremely viable program that tenders badly needed low-interest loan capital to over 7,000 medical students each year.

Student financial aid is an investment in America's future, with the benefits far exceeding the costs. The currently staggering pace of scientific and technological advances in our world makes its obvious that the nation's only hope of meeting the demands of a modern society is to educate America's youth to their fullest potential. Short-term remedies to achieve modest "savings" in these programs will cost our country dearly in the long run, since the ability of the United States to compete in the industrial age depends on its success in training the next generation of scientific and technical talent.

For the Medicaid program, the Administration is once again proposing to limit Federal matching payments. At a time when 33 million Americans have no health insurance, another 17 million are underinsured, and the unemployment rate is hovering around 7 percent, the AAMC strongly believes that any reduction in Medicaid funding would be tantamount to completely turning our backs on the nation's poor and disadvantaged. Nothing short of full federal participation should be provided for these vital programs.

The Association regrets that time constraints do not permit us to speak to or enlarge upon other important health programs that serve sound public purposes and should be continued at reasonable levels --- the National Institute for Handicapped Research, the National Center for Health Services Research and Technology Assessment, the National Center for Health Statistics, and the National Institute for Occupational Safety and Health.

Senator PROXMIRE [presiding]. Thank you very much, Dr. Petersdorf. I very much appreciate it. I am sorry I was tardy and the chairman had to leave.

I would think that one action that the Congress could take that would be helpful in retaining and encouraging people to continue their medical education would be tort reform. In other words, stopping the malpractice fever that has grasped the country. I think attorneys are abusing the system seriously.

I have a son-in-law who is a doctor. He is quitting medicine, after a distinguished career, to go to law school. You can understand why. [Laughter.]

Dr. PETERSDORF. I heartily agree.

Senator PROXMIRE. Are you concerned about the health education assistance loans [HEAL] default rate?

Dr. PETERSDORF. I believe that every one of those loans should be repaid. We have done very much better in terms of the medical schools. There are good data, which I will submit for the record, to prove that. I think there should be no defaults at all, and at least of all should there be defaults from people who have had a successful career and practice in science. I think they should be able to repay them.

The question seems to lead to the fact that there should be no defaults. I have some concern.

Senator PROXMIRE. I am sure there are going to be some defaults. Thank you very much. We would appreciate very much getting that information for the record. Thank you, Dr. Petersdorf.

STATEMENT OF MARY ANNE FREEDMAN, PRESIDENT-ELECT, ASSOCIATION FOR VITAL RECORDS AND HEALTH STATISTICS

Senator PROXMIRE. Our next witness is Mary Anne Freedman, president-elect of the Association for Vital Records and Health Statistics, from the State of Vermont. We are happy to have you testify. Go right ahead.

Ms. FREEDMAN. I am Mary Anne Freedman, president-elect of the Association for Vital Records and Health Statistics. Our organization represents health statistics programs in State and local health departments. We are affiliated with the Association of State and Territorial Health Officials, which shares the concerns I will express in this testimony.

I would like to highlight some issues related to the budget of the National Center for Health Statistics [NCHS]. NCHS is the primary health statistics agency in the Federal Government. It collects and analyses a variety of data that are critical to maintaining and improving the health of our citizens.

The most fundamental data produced by NCHS are vital statistics. This very important data system is used to monitor health problems, such as infant mortality, incidents of low birth weight, and cancer mortality. It provides the Census Bureau with data to make population estimates and projections and is also essential to medical research and is a major source of data for the National Cancer Institute and the other institutes of health.

The national vital statistics system is a cooperative effort between Federal and State governments. Data are collected by States, computerized and provided to NCHS under contract. Payment for these data is effected through a mutually agreed upon formula, based on a philosophy that the costs should be shared between the States and the Federal Government. NCHS has stated that the Federal Government should fund at least 33 percent of costs directly related to the production of State data tapes. This view is shared by the House Committee on Energy and Commerce, the National Committee on Vital and Health Statistics, the Office of the Assistant Secretary for Health, the Association of State and Territorial Health Officials, and our organization.

Despite this fact, the fact that NCHS has managed to maintain level funding in current dollars for the National Vital Statistics Program, increased costs in State offices have caused the funding share supported by the Federal Government to decline from over 40 percent in the late 1970's to the current level of 26.5 percent. The projected fiscal year 1985 share of approximately 25 percent continues this decline in the Federal level of support.

The impact of these funding reductions on State vital statistics programs is considerable. Without adequate funding, States must make programmatic cuts that will affect their ability to provide data that meets NCHS' contractual standards.

Ultimately, if the Federal share continues to decline, States may be forced to drop out of the vital statistics system. Alternatively, NCHS may find it necessary to reduce the scope of work in the vital statistics contracts. In either case, there will be a loss of critical information, data from individual States may be missing or whole data sets may not be available at all.

Thus, at a time when the Nation needs quality data to make informed decisions, there is a very real potential that the needed information may not be there.

The recent Gramm-Rudman-Hollings sequestrations have already had adverse effects on the National Vital Statistics Program. NCHS absorbed most of its $2 million cut by reducing the period of performance on many State vital statistics contracts from 1 year to 6 or 9 months.

Recently, NCHS has been urged to expand its vital statistics system into new areas such as the linkage of birth and infant deaths. While States would like to participate in these efforts, we have difficulty expanding the system at a time when the funding base for the current program is eroding.

The proposed fiscal year 1987 budget does not contain sufficient moneys to enable the States to continue providing vital statistics data to NCHS at their current levels of effort. We continue to fall further behind in achieving the recommended Federal funding level.

To prevent the decline of the National Vital Statistics Program, we urge you to support the President's budget request which gives NCHS an additional $2.3 million, primarily to replace the fiscal year 1986 sequestration. We also urge you to provide NCHS with an additional $2 million, to bring the Federal share to approximately 33 percent of the data acquisition costs.

While this is a small amount of money in the context of the Federal budget, we ask you not to overlook it because of the major impact the vital statistics system has on all public health programs.

PREPARED STATEMENT

Thank you for providing me with the opportunity to present our concerns to you. I would be happy to answer any questions you may have.

[The statement follows:]

STATEMENT OF MARY ANNE FREEDMAN

Mr. Chairman, I am Mary Anne Freedman, President-Elect of the Association for Vital Records and Health Statistics. Our organization represents health statistics programs in state and local health departments. We are affiliated with the Association of State and Territorial Health Officials, which shares the concerns I will express in this testimony.

I would like to highlight some issues related to the budget of the National Center for Health Statistics. NCHS is the primary health statistics agency in the federal government. Its responsibilities include collecting and analyzing data that are critical to maintaining and improving the health of our citizens. Some examples are the National Vital Statistics System, from which we get information about the natality and mortality experience of our population; the National Health and Nutrition Examination Survey, which provides data on nutritional and physiological health in the United States; the National Health Interview Survey, a principal source of information on the health, illness, and disability status of the population; and the National Ambulatory Medical Survey and the National Hospital Discharge Survey which provide information on the utilization of health care services.

Of these, the vital statistics produced by NCHS are the most fundamental. The National Vital Statistics System is the single most important data base for assessing the health of the United States population. It is used to monitor health problems such as infant mortality, teenaged suicide, incidence of low birthweight, heart disease and cancer mortality. This system provides the Census Bureau with data necessary for making population estimates and projections. It is also essential to medical research and is a major source of data for the National Cancer Institute and the other institutes of health.

The National Vital Statistics System is a cooperative effort between federal and state governments. Data are collected by states, processed, and provided to NCHS, in computerized form, under contract. Payment for vital statistics data is effected through a mutually agreed upon formula, which provides for the equitable distribution of funds among states. The formula is based on the philosophy that costs in the Vital Statistics Program should be shared between the states and the federal government. NCHS has stated that the federal government should fund at least 33 percent of costs directly related to the production of the state data tape, as determined by the formula.[1] The House Committee on Energy and Commerce shares NCHS's view of the appropriate federal funding share,[2] as do the National Committee on Vital and Health Statistics,[3] the Office of the Assistant Secretary for Health,[4] the Association of State and Territorial Health Officials,[5] and our organization.[6]

Despite the fact that NCHS has managed to maintain level funding (in current dollars) for the Vital Statistics program, increased costs in state offices have caused the funding share supported by the federal government to decline from over 40 percent in the late 1970's to the current level of 26.5 percent. The projected FY 1987 share of approximately 25 percent continues this decline in the federal level of support. Thus, over the past several years, the states have experienced a significant (34 percent) reduction in funding.

The impact of these funding reductions on state vital statistics programs is considerable. Without adequate funding, states must make programmatic cuts, including staffing reductions. These cuts will affect their ability to provide data that meet NCHS's contractual standards. As this situation continues over time the problem becomes more acute. Ultimately, if the federal share continues to decline, states may be forced to drop out of the Vital Statistics System. Alternatively, in order to retain states in this voluntary system, NCHS may find it necessary to reduce the scope of work in the vital statistics contracts. That is, NCHS may not be able to purchase all of the data it currently obtains under these contracts. In either case, there will be a loss of critical information: data from individual states may be missing, or data components (e.g., race, ethnicity, prenatal care) may not be available at all. Thus, at a time when the nation needs quality data to make informed decisions, there is a very real potential that the needed information may not be available.

The recent Gramm-Rudman-Hollings sequestrations have already had adverse effects on the vital statistics program. When NCHS was required to cut $2.0 million from its FY 1986 budget, the only major block of uncommitted funds was in Vital Statistics. Thus, NCHS absorbed $1.7 million of its Gramm-Rudman-Hollings cut by reducing the period of performance on many state Vital Statistics contracts from one year to six or nine months.

In recent months, health professionals have urged NCHS to expand the Vital Statistics System into two new areas: the linkage of birth and infant death certificates to enable more intensive analysis of infant mortality, and increased analysis of occupationally-related mortality. Several Congressional Subcommittees have also expressed interest in these activities. While states recognize the importance of these efforts, and would like to participate, we have difficulties expanding the Vital Statistics System at a time when the funding base for the current program is eroding.

NCHS is an organization with responsibility for a variety of important public health data systems. It must balance its resources among those programs. We in the states recognize this and do not want to see funds diverted within NCHS from one important program to another. However, we believe that the Vital Statistics program is the most important of NCHS's activities. In the face of budget stringencies, even this most fundamental program is in trouble.

The proposed FY 1987 budget does not contain sufficient moneys to enable the states to continue providing vital statistics data to NCHS at their current level of effort. We continue to fall further and further behind in achieving the recommended federal funding level. To prevent the decline of the national vital statistics program we urge you to support the President's budget request which gives NCHS an additional $2.3 million primarily to replace the FY 1986 sequestration. We also urge you to provide NCHS with an additional $2.0 million to bring the federal share to approximately

33 percent of data acquisition costs. This is a small amount of money in the context of the federal budget. However, even though it is small, we ask you not to overlook it because of the major impact the Vital Statistics System has on all public health programs.

Thank you for providing me with the opportunity to present the concerns of the Association for Vital Records and Health Statistics. I would be happy to answer any questions.

REFERENCES

1. Report of the Working Group on the Completion of the Vital Statistics Cooperative Program, DHHS, May 21, 1982.
2. House Report 98-818, pg 8, June 4, 1984. (Report of the House Committee on Energy and Commerce to accompany HR 5496, the reauthorization of NCHSR and NCHS.)
3. Report of the National Committee on Vital and Health Statistics to the Assistant Secretary for Health on the Vital Statistics Cooperative Program, September 20, 1984.
4. Letter from James F. Dickson III, M.D., Acting Assistant Secretary for Health, to Robert H. Barnes, M.D., Chairman, National Committee on Vital and Health Statistics, January 17, 1985.
5. ASTHO endorsement of AVRHS Resolution 85-4, March 3, 1986.
6. AVRHS Resolution 85-4; on the Report of the United States National Committee for Vital and Health Statistics on the Cooperative Health Statistics Program, August 16, 1985.

Senator PROXMIRE. Thank you very much, Ms. Freedman. The gathering of statistics of this kind is relatively inexpensive. The cost is very low compared to the cost of so much else that we have in the budget, particularly with respect to health. If we do not know what we are doing, and the statistics are absolutely essential for us to understand the effect of our actions, it seems to me our policies are going to be very misguided and there is going to be a lot of waste.

I am all for your program. You say that you urge the Congress to support the President's budget request?

Ms. FREEDMAN. As a minimum; yes.

Senator PROXMIRE. This is a new twist. Unless you are talking to the military people, we rarely get that approach in this area, where the administration requests have been for very meager amounts, often for drastic cuts. I appreciate it. I think that you have made a reasonable request.

I have one question. Are the various State peer review organizations participating in each State's vital statistics program?

Ms. FREEDMAN. In general, no. They are independent.

Senator PROXMIRE. Is there data sharing between these two entities?

Ms. FREEDMAN. Yes; there is.

Senator PROXMIRE. Don't you think they ought to work together, in view of the fact that it is so essential that the peer review organizations understand the data?

Ms. FREEDMAN. The peer review organizations use some vital statistics data but they are primarily using hospital discharge data and administratively, they are not typically part of State government.

Senator PROXMIRE. Thank you very much.

STATEMENT OF DR. KEVIN MARTIN, CHAIRMAN OF THE PUBLIC POLICY COMMITTEE, AMERICAN FEDERATION FOR CLINICAL RESEARCH

Senator PROXMIRE. Our next witness is Dr. Kevin Martin, chairman of the public policy committee, American Federation for Clinical Research [AFCR]. Dr. Martin, we are happy to have you.

Dr. MARTIN. Senator Proxmire, I am Dr. Kevin Martin. I am an associate professor of medicine in the Renal Division, Washington University, St. Louis. I am pleased to be here today to present you with the views of the more than 12,000 members of the American Federation for Clinical Research.

The AFCR, whose public policy committee I chair, is a national organization of young medical investigators whose chief interest is discovering new medical knowledge aimed at the understanding and treatment of human disease. My own specialty area of nephrology is just one of the many practiced by the AFCR members.

The AFCR congratulates the subcommittee for your demonstrated support and understanding of the issues surrounding medical research. The benefits which the Nation receives from its Federal investment largely funded through the National Institutes of Health are numerous and include improved health care, new products, economic incentives, and international prestige.

It is estimated that approximately $13 are returned for every $1 invested. In light of these significant results, we believe that the vital biomedical research enterprise should be maintained and that all the current services and programs should be fully funded, plus a modest growth in some areas.

The current pace of development of new medical knowledge has been the result of consistent congressional investment. However, the President has proposed to reduce the NIH budget by more than 10 percent, cutting spending in every Institute and every programmatic mechanism.

The AFCR joins with over 100 organizations in the ad hoc group for medical research funding to support an alternative NIH budget of $6.079 billion. This amount would fund NIH at the same programmatic level you appropriated in fiscal year 1986, plus a small increase, 1.4 percent, for one or two especially important programs which deserve additional funding.

In addition, the AFCR has identified four areas in the fiscal year 1987 appropriations, which we believe are especially important for maintaining the pace of medical advancement now and in the years ahead.

First, we recommend the level of awards currently being funded should be maintained and that all investigator-initiated grants be fully funded at the study section approved levels. This would enable NIH to award approximately 32 percent of approved grant applications, slightly less than this year, but significantly more than the 27 percent that the President's budget would fund.

The AFCR strongly urges you to recommend the appropriation of at least $3.5 billion for extramural research grants.

Second, we recommend that the current general clinical research centers be fully funded and that a few more centers be awarded. These centers are a place for transferring scientific discoveries from the laboratory to the bedside, and are an important entry point for future clinical investigators. To facilitate the conduct of clinical research, the AFCR recommends that $105 million be appropriated to the General Clinical Research Centers Program.

Third, the AFCR recommends that research training programs be funded at the level recommended by the National Academy of Sciences, that is for 11,075 trainees. Rigorous training is essential to achieve success as an independent investigator and is particularly important to curtail the declining number of physician investigators.

The President's recommendation of almost 2,000 fewer trainees would have serious implications for future research. The AFCR urges an appropriation for $238 million for research training.

Fourth, the AFCR recommends that research career development awards for advanced fellows and young faculty be fully funded and the number of awards be increased beyond the level currently being supported.

These awards are critical in encouraging young physicians to continue investigative careers and subsequently achieve their potential. The AFCR recommends $91 million be appropriated for this program.

In summary, the AFCR recommends that your subcommittee support the appropriation of $6.079 billion for NIH in fiscal year 1987. This sum would support all of the current NIH research activities by being mindful of the effort to reduce the Federal budget.

We believe that our request is consistent with health research needs of the country and takes advantage of unparalleled opportunities available in biomedical research. If we can work together, these opportunities will give us new cures, treatments, and breakthroughs and continue the investment the American people have made in biomedical research.

PREPARED STATEMENT

On behalf of the AFCR, I thank you for your time.

[The statement follows:]

Statement of Dr. Kevin Martin

I am pleased to be here today to present to you the views of the 12,000 members of the American Federation for Clinical Research (AFCR). We are an organization of young clinical investigators whose chief interest is discovering new medical knowledge aimed at the understanding and treatment of human disease. We are employed throughout the nation by medical schools, teaching hospitals and research institutions. We are unique in that no single subspecialty dominates our membership. We place particular emphasis on encouraging young medical researchers and view the role of federal initiatives for developing new talent as vital to the advancement of American medicine.

The AFCR is deeply concerned about the appropriation for the National Institutes of Health (NIH) as are the members of this subcommittee. You have clearly demonstrated your support and understanding of the issues surrounding medical research. However, this year the growing budgetary crisis has confronted the Congress with the need to address deficit reduction. All Americans are asking the Congress to make tough choices. We support these national efforts to reduce spending and realign priorities. But we do not believe that sharply reducing our nation's investment in biomedical research and development is the best way to accomplish this goal. The appropriation which we support for the NIH is less than optimal funding yet will maintain the vitality of the biomedical research enterprise. We believe that the nation continues to want improved health and an investment in a better future for our children.

The benefits which the nation receives, and which literally every person receives, from the NIH investment are numerous. There is a direct relationship between the work done in the nation's research centers and better health care. The annual expenditure on health care is $2,000 per person, while the annual federal investment in medical research to reduce that cost and improve health is only $25 per person! In addition, the federal investment provides industry with the basic research it needs to produce new products, creates jobs for thousands of workers, and provides the nation with international prestige as a leader in biomedical research. Studies show that the rate of return on every $1 invested in medical research is $13.00. The nation needs this fuel for its economy. Over $40 billion is contributed annually to the GNP from medical research discoveries that are now used in non-health related products. These many benefits will not accrue if we do not continue to invest in our future.

The federal investment in health research and development is largely accomplished through the NIH. Therefore, when the President proposes, as he did in February, to reduce the NIH budget by more than 10%, he is actually proposing to slow development of new knowledge and reduce the rate of new medical breakthroughs. The President's budget would cut spending in every NIH institute and in every programmatic mechanism. The ultimate impact of such a proposal would be felt by individual Americans, though in the short term, the more obvious loss is the excellent research proposals which go unfunded and the new young researchers who choose other, more stable careers.

The current pace of development of new medical knowledge has been the result of a consistent Congressional investment in the NIH. Advancement in science and medicine occurs slowly; sometimes imperceptably, across many disciplines. The federal investment in medical research has produced a deep reservoir of knowledge and experienced personnel. That reservoir must be continually replenished and young scientists who will provide the new ideas for the next generation must be trained, if we are to achieve the promise of the prevention and cure of countless previously intractable conditions.

As an alternative to the President's proposal, the AFCR supports the alternative budget developed by the Ad Hoc Group for Medical Research Funding. This group of over 100 organizations develops each year a responsible NIH budget which addresses what we believe are the reasonable funding needs of biomedical research. For FY87 the Ad Hoc Group proposes that the NIH be funded at the same programmatic level you appropriated in the FY86 budget, plus a small amount of growth (1.4%) for one or two especially important programs which deserve additional funding. To do this would cost $6.079 billion. The AFCR urges you to carefully consider this "current services" budget which would continue the NIH programs and yet addresses the needs of the nation for restrained federal spending.

The AFCR has identified four areas in the FY87 NIH appropriation which we believe are especially important for maintaining the pace of medical advancement now and in the years ahead:

1) investigator - initiated grants, at the current level of new and competing renewal awards, should be fully-funded at study section recommended levels (estimated cost: $3.4 to $3.6 billion)
2) General Clinical Research Centers should be fully funded with a slight increase in the number of such centers (estimated cost: $105 million)
3) research training funds should support the number of trainees recommended (11,075) by the National Academy of Sciences, (estimated cost: $238 million)
4) research career development awards for young faculty should achieve modest growth beyond last year's level of effort (estimated cost: $91 million)

First, we recommend the level of awards currently being funded should be maintained and that all investigator - initiated grants be fully-funded at study section recommended levels. This would enable NIH to award grants to approximately 32% of approved grant applications, slightly less than the anticipated FY86 rate of award, but significantly more than the 27% the President's budget would fund. This is in fact a modest request and in keeping with current budgetary constraints. The AFCR believes that the eventual goal of grants policy should be to support all excellent research opportunities through funding of 50% of approved grant applications. This would allow optimal progress and ensure that promising research initiatives were tested.

By maintaining the current level of research grant awards a steady and consistent level of funding would be achieved. This is particularly important to new entrants into the ranks of researchers. When only a select few of those who apply for NIH funding receive a grant the perception of the probability of success in a biomedical research career is diminished. Because NIH provides almost two-thirds of all national support for health related research and development in the country's centers of higher education, decreases in NIH grant funding have profound implications for medical researchers. Previous NIH appropriations recommended by your subcommittee and passed by the Congress have provided AFCR's young investigators with a very positive sense of the future in health research. The AFCR strongly urges you to recommend an appropriation of at least $3.5 billion for extramural research grants.

Second, the AFCR recommends that all current General Clinical Research Centers (GCRC) be fully funded and that a few more centers be awarded. The GRC program is of special significance for clinical research as a GCRC is both a place for transferring scientific discoveries from the laboratory to the bedside and an entry point for future clinical investigators. GCRC units have been established at 78 medical centers thoughout the nation. Within each center patient beds provide a focal point for clinical research, where more than 3,500 projects are conducted each year. At any one center as many as 100 different projects may benefit from the program. In addition the GCRCs are influential in stimulating young researchers through on-site medical student exposure to clinical research and through the very selective Clinical Associate Physician program. To facilitate the conduct of clinical research the AFCR recommends that at least $105 million be appropriated to the GCRC program.

Third, the AFCR recommends that research training programs be funded at the level recommended by the National Academy of Sciences (NAS) Congressionally mandated continuing study of the nation's overall need for biomedical research personnel. The NAS Committee recommends that 11,075 trainees should be supported by the National Research Service Awards program in FY87. Each of these training positions can be thought of as nurturing future new developments in medical knowledge. Analyses of successful new NIH grant recipients show that long and rigorous training is crucial to success as an independent investigator. Both M.D. and Ph.D. graduates and undergraduates benefit; however the role of the federally sponsored research training for physician investigators is particularly important. The President's recommendation of almost 2,000 fewer trainees would have serious future implications for research. The AFCR recommends that approximately $238 million be appropriated to support all of the NAS recommended trainees.

Fourth, the AFCR recommends that research career awards for advanced fellows and young faculty be fully funded and that modest growth in the number of awards be initiated. The five award programs in the "K-series" are very competitive and provide needed support for competitively selected promising young scientists to make the transition from promising research trainees to successful independent investigators. Because the number of M.D. investigators has been shown to be declining, the research career awards are particularly critical for clinical research. These awards encourage physicians to continue investigative careers and subsequently to achieve their potential. The AFCR recommends that $91 million be appropriated for such research career development awards.

In summary, the AFCR recommends that your subcommittee support an appropriation of $6.079 billion for NIH in FY87. This sum would support all of the current NIH research activities while being mindful of the national effort to reduce the federal budget. We believe that our request is consistent with the health research needs of the country and takes advantage of the unparalleled opportunities currently available in biomedical research. If we work together those opportunities will become new medical cures, treatments and research breakthroughs, and the investment the American people have made in biomedical knowledge will continue to compound. On behalf of the AFCR I thank you for your time and will be happy to answer any questions.

Senator PROXMIRE. Thank you very much, Dr. Martin.

Dr. Martin, is the AFCR concerned about the increasing percentage of each research dollar that is going to pay for indirect costs?

Dr. MARTIN. Yes; the indirect cost is clearly an important issue, and it is certainly worth our serious consideration. At the present time, we believe this is under study by a group of the National Academy of Sciences who are looking at this with the Office of Management and Budget [OMB] in great detail, and hopefully some consensus can be reached in this regard.

From the point of view of the researchers in the field, obviously we would like the research dollars to be applied to grants. Of course, there has to be some compromise in terms of the provision of all the facilities under indirect costs, so we are anxious that some consensus be reached in this regard.

Senator PROXMIRE. Thank you very much, sir. We appreciate your testimony.

STATEMENT OF ALFRED E. HARPER, PRESIDENT, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

Senator PROXMIRE. Our next witness is Dr. Alfred Harper, Federation of American Societies for Experimental Biology [FASEB], professor of nutrition at the University of Wisconsin.

Mr. HARPER. Mr. Chairman and members of the subcommittee, thank you for your introduction.

I would like to emphasize that FASEB is a nonprofit organization whose purpose is to develop and disseminate new knowledge in life sciences, and our 28,000 members in seven constituent societies represent research, educational, and clinical centers across the United States.

I am here as a representative of these working scientists, who are actively engaged in medical and biological research.

I have submitted written testimony that I wish to have included in the record. I would like to emphasize a few points in particular.

Senator PROXMIRE. Without objection your written statement will be inserted in full.

[The statement follows:]

STATEMENT OF ALFRED E. HARPER

Mr. Chairman, members of the subcommittee, I am Alfred E. Harper, President of the Federation of American Societies for Experimental Biology (FASEB). I am also Professor of Nutritional Sciences and Biochemistry at the University of Wisconsin.

FASEB is a nonprofit organization whose purpose is to develop and disseminate new knowledge in the life sciences through its meetings and publications. Our 28,000 members in seven constituent societies represent research, educational and clinical centers across the United States. Since our founding in 1912, the Federation has counted 108 Nobel Laureates among its membership. That membership is overwhelmingly composed of working scientists actively engaged in biological and biomedical research, and it is the voice of the working scientist we wish you to hear today.

Let me make it clear that you and this subcommittee have been exemplary in your support of basic biological research and, as researchers, we deeply appreciate your commitment to this cause and your sustained efforts on our behalf.

When we came before you last year to testify on funding for the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration, we were very conscious of the impact the enormous federal deficit could have on support for biomedical research and of the fiscal implications continued high deficits have for the future of all federal programs. This year the compelling new factor is the Gramm-Rudman-Hollings law designed to balance the budget by 1991. Gramm-Rudman-Hollings could have a devastating impact on basic research. Budget crafters must recognize, however, as they work toward a balanced budget, that basic biological research has a legitimate claim to a reasonable portion of scarce fiscal 1987 federal dollars because it is undertaken for the benefit of all Americans and, I might add, of all mankind. While the for-profit and nonprofit sectors do make contributions to the support of this research, it is the federal government that must shoulder the greatest financial burden if this unique and humanitarian effort is to continue and to pay dividends in the years ahead.

Vaccine development is a good example of the important role the federal government plays in basic research. According to a report on vaccines by the

Institute of Medicine of the National Academy of Sciences, "The process of vaccine innovation (from basic research to commercial availability) rarely begins in industry...The basic research necessary to identify pertinent characteristics of the pathogen and host response, often extremely time-consuming and expensive, usually is conducted in federally funded academic or government laboratories, such as those of the National Institute of Allergy and Infectious Diseases..."

There is example after example of the crucial role of federal support in basic biomedical research. Our progress against cancer, heart disease and stroke, to cite just a few areas, is a direct result of federally sponsored research whose primary objective is not profit, but disease treatment and cure as well as a fuller understanding of the processes of life. The success of this unique undertaking depends on the talents and abilities of thousands of dedicated scientists at universities and research centers throughout the United States.

The price of this success is an adequate financial commitment by the federal government, not merely for this year or next, but over the long haul. It is the nature of basic research that it requires a long-term commitment of dollars as well as public patience and trust if there is to be continued hope of producing the life-saving results we all seek.

Dishearteningly, but not surprisingly in view of recent history, the President's fiscal 1987 budget request for NIH is $4.9 billion, a decrease of more than $400 million from the fiscal 1986 congressional appropriation. Under this plan, NIH would support only 5,104 new and competing grants, down from 6,100 in fiscal 1986. The number of research centers would drop from the fiscal 1986 level of 550 to 523 and the number of trainees supported would fall from 9,947 to 9,250. For Alcohol, Drug Abuse and Mental Health Administration research, the Administration is requesting $318.9 million, a five percent decrease below the fiscal 1986 research funding level of $335.6 million. Investigator-initiated new and competing grants would drop from 505 in fiscal 1986 to 448 in fiscal 1987. ADAMHA training programs would be cut back from the $41 million enacted level to only $18.5 million in fiscal 1987.

These proposed cuts are deeply disturbing. The consequences of reduced funding levels for NIH and ADAMHA in fiscal 1987 reverberate far into the future. A research project is not only a sum of money expended over a particular fiscal year--that is only one aspect of this commitment of federal funds. There is momentum to the acquisition of new knowledge, which is lost when federal funding dips unexpectedly. The boundaries between disciplines are increasingly being bridged--a discovery in one area can ignite a whole stream of ideas in another, any one of which can produce long-sought cures as well as important savings in health care costs as long as steady federal funding exists to support these endeavors. The cost of research forgone now cannot be measured by the number of dollars saved and put toward a smaller deficit. Rather, it must be weighed in terms of human suffering not alleviated and the incalculable costs of lost scientific opportunity.

The progress of scientific knowledge and the momentum of discoveries also depends on our ability to recruit and train the next generation of scientists. The Administration budgets for NIH and ADAMHA tell our bright, inquisitive undergraduate and graduate students, our young, promising scientists and our established investigators that a career in federally-sponsored basic biological research may be unreasonably precarious. This instability not only drives trained researchers from the field but discourages promising young people from entering it--losses we cannot afford.

We join with the Ad Hoc Group for Medical Research Funding, a coalition of more than 150 organizations, in recommending a fiscal 1987 funding level for NIH of $6.079 billion. This funding level represents an increase of about $86 million or 1.4 percent over a current services budget. Our recommendation would restore the cuts made by the Administration budget request in a number of areas, including biomedical research support grants, and would continue most NIH programs at their fiscal 1986 level of operation. In addition, the Ad Hoc Group proposal would provide funds sufficient to raise the number of research trainees to the level recommended by the National Academy of Sciences, to upgrade and renovate primate centers and other facilities, to strengthen support for clinical trials through general clinical research centers and increase the number of specialized and comprehensive research centers.

For NIH competing and non-competing research project grants, the Ad Hoc Group recommends a current services dollar level for full funding at study section recommended amounts--a total of between $3.4 billion and $3.6 billion. This level should be sufficient to fund 6,100 new and competing NIH grants in fiscal

1987. FASEB believes Congress spoke strongly and acted wisely in increasing the number of new and competing grants to 6,100 in fiscal 1986. We have fought long and hard to reach this level. FASEB recommends that the 6,100-grant level be maintained in the coming fiscal year and that the number supported by the subcommittee be cited.

The investigator-initiated research project grant continues to be the keystone of the NIH effort because it explores questions at the cutting edge of research, offering the greatest hope for progress against disease. The number of new and competing grants is the key indicator of the health of the NIH research program. If Congress fails to make the grant level a clear priority, OMB has shown it will not hesitate to hold grants near the 5,000 level, a serious setback for research.

For the Alcohol, Drug Abuse and Mental Health Administration we join with the Ad Hoc Group in recommending a research funding level of $465 million. This proposal is consistent with the Institute of Medicine recommendation that ADAMHA's research budget be doubled from 1986 to 1991. This increase would allow for an expanded level of new and competing grants, growth in Research Centers and Research Scientist Development Awards with a focus on young investigators, an increased number of trainees, and badly needed renovation of facilities and equipment.

We urge this subcommittee to continue its enlightened investment in the health of our people, and that of people throughout the world, by providing funding levels for NIH and ADAMHA that allow us to maintain the momentum of biological, biomedical and behavioral research. As working scientists, we assure you that your support, particularly of the individual investigator-initiated research grant, is not only essential to our work, but the reason we have been so successful in our endeavors.

I would be happy to answer any questions you may have.

Scientific Basis for the Support of Biomedical Science

Julius H. Comroe, Jr., and Robert D. Dripps

Our project had only one goal: to demonstrate that objective, scientific techniques—instead of the present anecdotal approach—can be used to design and justify a national biomedical research policy.

Our interest in this project began in 1966 when President Lyndon Johnson said, "Presidents . . . need to show more interest in what the specific results of research are—in their lifetime, and in their administration. A great deal of *basic* research has been done . . . but I think the time has come to zero in on the targets—by trying to get our knowledge fully applied. . . . *We must make sure that no lifesaving discovery is locked up in the laboratory* [italics ours]."

The position of the Johnson Administration on basic research was bolstered by a preliminary report of a study, "Project Hindsight," commissioned by the Department of Defense and published in 1966 (*1*). A team of scientists and engineers analyzed retrospectively how 20 important military weapons came to be developed. Among these were weapons such as Polaris and Minuteman missiles, nuclear warheads, C-141 aircraft, the Mark 46 torpedo, and the M 102 Howitzer.

Some of the conclusions of that study were as follows. (i) The contributions of university research were minimal. (ii) Scientists contributed most effectively when their effort was mission-oriented. (iii) The lag between initial discovery and final application was shortest when the scientist worked in areas targeted by his sponsor.

The President's words and the Department of Defense's report popularized a new set of terms such as research in the service of man, strategy for the cure of disease, targeted research, mission-oriented research, disease-oriented research, programmatic research, relevant research, commission-initiated research, contract-supported research, and payoff research. These phrases had a great impact on Congress and on the Office of Management and Budget and led to a sharp upsurge of contract research and commission-initiated research supported by the National Institutes of Health (NIH).

Medical and other scientists countered with carefully prepared case reports that illustrated the important contributions of basic, fundamental, undirected, nontargeted research to advances in medicine, social sciences, and physics (*2*).

Since 1966 there has been a continuing debate whether the federal government would get more for its biomedical research dollars if they were used to support clinically oriented research or if they were used to support research that was not clinically oriented.

We believe that the Department of Defense's study suffered from two factors. (i) Only a preliminary report has been released (and that 9 years ago) and even it is not yet widely available. (ii) Some who have read it have transferred conclusions drawn from that study on development of military weapons directly to biomedical research. However, the reports of those who countered Project Hindsight also suffered from one or both of two problems. (i) Some presented single case reports and so were anecdotal or "for instance" arguments. (ii) The cases were selected by those who did the study and so were subject to their bias.

It is easy to select examples in which

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basic, undirected, nonclinical research led to dramatic advance in clinical medicine and equally easy to give examples in which either clinically oriented research or development was all-important. A classic example of the great importance of research completely unrelated to clinical medicine or surgery was that of Wilhelm Roentgen. While studying a basic problem in the physics of rays emitted from a Crookes' tube, he discovered x-rays that immediately became vital for precise diagnosis of many diseases and later for the treatment of some. A classic example of the importance of mission-oriented research was that of Louis Pasteur. Pasteur, originally trained as a chemist, was employed by the French government as an industrial trouble-shooter. Among the problems assigned to him were the practical ones of how to keep wine from turning to vinegar, how to cure ailing silkworms, and how to save sheep dying of anthrax and chickens dying of cholera. The solution of these practical problems led Pasteur to discover bacteria and become the founder of modern bacteriology and the father of the germ theory of disease. A classic example of the importance to medicine of development (as opposed to research) was the mass production of penicillin in the United States in the early 1940's when it was required immediately for England's war effort and later for our own.

The anecdotal or "let me give you an example" approach provides fascinating after-dinner conversation and even interesting testimony before congressional appropriations committees. However, we believe that the time has come for the nation's biomedical research policy to be based on something more substantial than a preliminary analysis of weapons development by the Department of Defense and informal let-me-give-you-an-example arguments by concerned scientists, and that Congress and the Administration should require more than for-instances from proponents or opponents of any policy for the support of medical research. We believe that the design and the broad scope of our study avoid the weaknesses of previous studies and provide an example to show how long-term policies on support of biomedical research can be developed on an objective basis.

Scope of Our Study

Because the heart of our thesis is that the support of research should not be based on selected examples or anecdotes, it was mandatory that we study all of a broad field. We selected the field of cardiovascular and pulmonary diseases because these are responsible for more than half of all deaths in the United States each year and because we have some competence in evaluating research on the heart, blood vessels, and lungs, or know where to go for advice. To ensure that our study was concerned directly with the health of the nation and not with esoteric scientific discoveries, we directed our attention only to clinical advances since the early 1940's that have been directly responsible for diagnosing, preventing, or curing cardiovascular or pulmonary disease; stopping its progression, decreasing suffering, or prolonging useful life.

To avoid our own bias, we asked 40 physicians to list the advances they considered to be the most important for their patients. We then divided their selections into a cardiovascular and a pulmonary list and sent the appropriate list to 40 to 50 specialists in each field, asking each to vote on the list and to add additional advances that they believed belonged on the list. Their votes selected the top ten advances (Table 1). With these as a starting point, we worked retrospectively to learn why and how they occurred.

With the help of 140 consultants (*3*), including 46 interviewed personally, we identified the essential bodies of knowledge that had to be developed before each of the ten clinical advances could

Table 1. The top ten clinical advances in cardiovascular and pulmonary medicine and surgery in the last 30 years.

Cardiac surgery (including open-heart repair of congenital defects and replacement of diseased valves)
Vascular surgery (including repair or bypass of obstructions or other lesions in aorta, coronary, cerebral, renal, and limb arteries)
Drug treatment of hypertension
Medical treatment of coronary insufficiency (myocardial ischemia)
Cardiac resuscitation, defibrillation, "cardioversion" and pacing in patients with cardiac arrest, slow hearts, or serious arrhythmias
Oral diuretics (in treatment of patients with congestive heart failure or hypertension)
Intensive cardiovascular and respiratory care units (including those for postoperative care, coronary care, respiratory failure, and disorders of newborn)
Chemotherapy and antibiotics (including prevention of acute rheumatic fever and treatment of tuberculosis, pneumonias, and cardiovascular syphilis)
New diagnostic methods (for earlier and more accurate diagnosis of disease of cardiovascular and pulmonary-respiratory systems)
Prevention of poliomyelitis (especially of respiratory paralysis due to polio)

reach its current state of achievement. To make clear what we mean by this, let us consider cardiac surgery.

When general anesthesia was first put to use in 1846, the practice of surgery exploded in many directions, except for thoracic surgery. Cardiac surgery did not take off until almost 100 years later, and John Gibbon did not perform the first successful operation on an open heart with complete cardiopulmonary bypass apparatus until 108 years after the first use of ether anesthesia. What held back cardiac surgery? What had to be known before a surgeon could predictably and successfully repair cardiac defects? First of all, the surgeon required precise preoperative diagnosis in every patient whose heart needed repair. That required selective angiocardiography which, in turn, required the earlier discovery of cardiac catheterization, which required the still earlier discovery of x-rays. But the surgeon also needed an artificial heart-lung apparatus (pump-oxygenator) to take over the function of the patient's heart and lungs while he stopped the patient's heart in order to open and repair it. For pumps, this required a design that would not damage blood; for oxygenators, this required basic knowledge of the exchange of O_2 and CO_2 between gas and blood. However, even a perfect pump-oxygenator would

Table 2. Essential bodies of knowledge required for successful open-heart surgery.

Preoperative diagnosis of cardiac defects
Anatomic and clinical
Physiologic: electrocardiography, other noninvasive tests
Physiologic: cardiac catheterization
Radiologic: selective angiocardiography

Preoperative care and preparation
Blood groups and typing; blood preservation; blood banks
Nutrition
Assessment of cardiac, pulmonary, renal, hepatic, and brain function
Management of heart failure

Intraoperative management
Asepsis
Monitoring ECG, blood pressure, heart rate, EEG, and blood O_2, CO_2, and pH
Anesthesia and neuromuscular blocking agents
Hypothermia and survival of ischemic organs
Ventilation of open thorax
Anticoagulants
Pump-oxygenator
Elective cardiac arrest; defibrillation
Transfusions; fluid and electrolytes; acid-base balance
Surgical instruments and materials
Surgical techniques and operations

Postoperative care
Relief of pain
General principles of intensive care; recording and warning systems
Management of infection
Diagnosis and management of circulatory failure
Diagnosis and management of other postoperative complications
Wound healing

be useless if the blood in it clotted. Thus, the cardiac surgeon had to await the discovery and purification of a potent, nontoxic anticoagulant—heparin.

These are just a few examples; obviously Gibbon needed many more essential bodies of knowledge. Table 2 lists 25 that we believe he needed in 1954 before he could perform open-heart surgery with confidence in the result; we list all of these because some, such as antibiotics, are so commonplace in 1976 that we forget that even they once had to be discovered! For the ten advances, we identified 137 essential bodies of knowledge.

The knowledge essential for these advances has accumulated over decades or centuries from the lifetime work of many thousands of scientists. It was clearly impossible for us to read all of their publications to determine how and why the research of each was done. But, because we were determined to avoid the let-me-give-you-an-example approach, we did examine about 4000 published articles. Of these, we identified about 2500 specific scientific reports that were particularly important to the development of one or more of the 137 essential bodies of knowledge. We arranged these chronologically in 137 tables. From these, with the advice of consultants, we then selected more than 500 essential or key articles for careful study.

Why did we spend several years collecting and reading thousands of articles and arranging more than 2500 of these in 137 chronological tables before doing our final analysis? There were several reasons.

1) It was essential that we have tangible evidence that our selections came from painstaking, scholarly review and not from the imperfect memories of a group of scientists at a cocktail party.

2) The chronological lists facilitate analysis of lags between initial discovery and clinical application (to be reported elsewhere).

3) They emphasize to the reader that scientific advance requires far more work than that reported by the discoverer or by those who wrote key articles essential for his discovery. We believe that a major defect in education in science in high school and colleges is the perpetuation of the one person = one discovery myth (for example, Marconi = wireless; Edison = electric light) and that this is partly responsible for the anecdotal approach to national science policy. Without a long chronologic tabulation, such as the electrocardiography (ECG) list in Table 3, some might consider that Einthoven in 1903 invented the ECG in its 1976 form, without help from those who preceded or followed him. Chronological tables provide specific evidence for policy-makers that scientists earlier and later than the discoverer have always been essential to each discovery and its full development. A defect in tables is that they can convey only a bit of the message, because even a long list includes only a small fraction of the good, original research that helped to move us away from complete ignorance toward full knowledge.

Definition of a Key Article

1) It had an important effect on the direction of subsequent research and development, which, in turn, proved to be important for clinical advance in one or more of the ten clinical advances under study.

2) It reported new data, new ways of looking at old data, a new concept or hypothesis, a new method, new drug, new apparatus, or a new technique that either was essential for full development of one or more of the clinical advances (or necessary bodies of knowledge) or greatly accelerated it. The key article might report basic laboratory investigation, clinical investigation, development of apparatus or essential components, synthesis of data and ideas of others, or wholly theoretical work.

3) A study is not a key study (even if it won the Nobel Prize for its author) if it

Table 3. Chronological events in the development of electrocardiography. The scientists' names that are printed in boldface type indicate key articles.

Year of discovery	Scientist	Event and publication
B.C.	Ancients	Early manifestations of electricity: electric fish, rubbed amber, lodestone, terrestrial lightning
1660	von Guericke	First electricity machine (friction of glass and hand) [*Experimenta Nova Magdeburgica* (Jansson, Amsterdam, 1672), book 4, p. 147]
1745	von Kleist	Charge from electricity machine stored in glass bottle and delivered as static electric shock [Letter to Dr. Lieberkühn, 4 November 1745; J. G. Krüger, *Geschichte der Erde* (Luderwaldischen, Halle, 1746)]
1745–1750	Musschenbroek	Electricity stored in Leyden jar; shocks killed small animals [*Introductio ad Philosophiam Naturalem* (Luchtmans, Leyden, 1762), pp. 477–1132]
1752	**Franklin**	Kite and key used to charge Leyden jar from lightning; identity of lightning and electricity proved [*Philos. Trans. R. Soc. London* 47, 565 (1751–1752)]
1756–1757	Caldani	Nerve and muscle excited by discharge from Leyden jar [*Institutiones Physiologicae* (Pezzana, Venice, 1786)]
1780	Galvani	Stimulation of nerve by Leyden jar and "electricity machine" caused identical muscle contraction [*Bononiensi Scientiarum et Artium Instituto Atque Academia Commentarii* 7, 363 (1791)]
1786	**Galvani**	Concept of animal electricity [*Bononiensi Scientiarum et Artium Instituto Atque Academia Commentarii* 7, 363 (1791)]
1791	**Galvani**	Contraction of heart muscle produced by discharge from electric eel; contraction of muscle caused by injury current [*Dell'uso e dell'attività dell'arco conduttóre nelle contrazioni dei muscoli* (Tommaso d'Aquino, Bologna, 1794)]
1800	Volta	Electricity generated by dissimilar metals; voltaic pile or battery [*Philos. Trans. R. Soc. London Part 2* 90, 403 (1800)]
1839	Purkinje	Purkinje's fibers in the cardiac ventricles [*De Musculari Cordis Structura* (Friedlaender, Bratislava, 1839)]

Table 3 (continued).

Year of discovery	Scientist	Event and publication
1842	**Matteucci**	Muscle contracts if its nerve is laid across another contracting muscle [see Dumas, *C. R. Acad. Sci.* **15**, 797 (1842)]
1843	DuBois-Reymond	Action current in nerve as well as muscle [*Untersuchungen über Thierische Elektricität* (Reimer, Berlin, 1848–49)]
1852	Stannius	Ligatures demonstrating specific conduction paths in heart [*Arch. Anat. Physiol. Wiss. Med.* p. 85 (1852)]
1856	Kölliker and Müller	Frog muscle contraction used as indicator of cardiac currents [*Verh. Phys.-Med. Ges. Würzberg* **6**, 428 (1856)]
1875	Lippmann	Use of capillary electrometer [*Ann. Chim. Phys. Ser. 5* **5**, 494 (1875)]
1876	Marey	Refractory period in early cardiac systole [*Physiol. Exp. Trav. Lab. Marey* **2**, 63 (1876)]
1878	Engelmann	Studied electrical excitation of isolated frog heart [*Pflügers Arch.* **17**, 68 (1878)]
1879–1880	**Burdon-Sanderson and Page**	First ECG in intact animals (frogs) [*J. Physiol.* **2**, 384 (1879–80)]
1883	Gaskell	Sequence of contraction from sinus venosus to atria to ventricles [*J. Physiol.* **4**, 43 (1883)]
1887	**Waller**	First human ECG using Lippmann's capillary electrometer [*J. Physiol.* **8**, 229 (1887)]
1887	McWilliam	Noted fibrillary contractions of heart [*J. Physiol.* **8**, 296 (1887)]
1893	**His**	Atrioventricular bundle [*Arbeit. Med. Klin. Leipzig.* **14**, 14 (1893)]
1893	Kent	Atrioventricular bundle [*J. Physiol.* **14**, 233 (1893)]
1897	Ader	Thread or string galvanometer [*C. R. Acad. Sci.* **124**, 1440 (1897)]
1903	**Einthoven**	Sensitive string galvanometer for measuring human ECG; telemetry of ECG signals [*Pflügers Arch.* **99**, 472 (1903)]
1906	Tawara	Atrioventricular node [*Das Reizleitungssystem des Säugethierherzens* (Fischer, Jena, 1906)]
1907	Keith and Flack	Sinoatrial node, mammals [*J. Anat. Physiol.* **41**, 172 (1907)]

Table 3 (continued).

Year of discovery	Scientist	Event and publication
1908	Mackenzie	Polygraph, venous pulse and arrhythmias [*Diseases of the Heart* (Frowde, London, 1908)]
1909–1920	Lewis	ECG and arrhythmias in man (numerous articles in *Heart*, a magazine he founded)
1913	Einthoven, Fahr, de Waart	Equilateral triangle theory of ECG [*Arch. Ges. Physiol.* **150**, 275 (1913)]
1914	Garrey	Mechanisms of flutter and fibrillation; "circus" movements [*Am. J. Physiol.* **33**, 397 (1914)]
1915	Lewis and Rothschild	Excitation wave in dog heart [*Philos. Trans. R. Soc. London Ser. B* **206**, 181 (1915)]
1918	Smith	ECG changes after ligating a branch of coronary artery in dogs [*Arch. Int. Med.* **22**, 8 (1918)]
1926	Rothberger	Arrhythmias in man [in *Handbuch der Normalen und Pathologischen Physiologie* (Springer, Berlin, 1926), vol. 7]
1927	Wenckebach and Winterberg	Arrhythmias in man [*Die Unregelmässige Herztätigkeit* (Engelmann, Leipzig, 1927)]
1930	Wilson	Laws of distribution of potential differences in solid conductors; modern theory of ECG [*Am. Heart J.* **5**, 599 (1930)]
1939	Hodgkin and Huxley	Transmembrane action potential recorded in giant axone of squid [*Nature (London)* **144**, 710 (1939)]
1946 1949	Graham and Gerard Ling and Gerard	First measurement of transmembrane potential in skeletal muscle with intracellular microelectrodes [*J. Cell. Comp. Physiol.* **28**, 99 (1946); *ibid.* **34**, 383 (1949)]
1949	Coraboeuf and Weidmann	Intracellular electrode to record mammalian cardiac potentials [*C. R. Seances Soc. Biol. Paris* **143**, 1329 (1949)]
1951	Draper and Weidmann	Intracellular electrode used to measure transmembrane potentials of heart muscle cells [*J. Physiol.* **115**, 74 (1951)]
1958	Alanís, González, López	Electrical activity of bundle of His [*J. Physiol.* **142**, 127 (1958)]
1960	Giraud, Peuch, Latour	Electrical activity of bundle of His in man [*Bull. Acad. Natl. Med. Paris* **144**, 363 (1960)]

Table 3 (continued).

Year of discovery	Scientist	Event and publication
1967–1968	**Scherlag** *et al.*	Recording from bundle of His by cardiac catheter in man [*J. Appl. Physiol.* **22**, 584 (1967); *ibid.* **25**, 425 (1968)]
1967	Watson, Emslie-Smith, Lowe	Recording from bundle of His in patient undergoing cardiac catheterization [*Am. Heart J.* 74, 66 (1967)]

has not yet served directly or indirectly as a step toward solving one of the ten clinical advances.

4) An article is a key article if it described the final step in the clinical advance, even though it was an inevitable step requiring no unusual imagination, creativity, or special competence (for example, first person to report on a new drug in humans even though basic work on animals had been done and results in humans were largely predictable) (*4*).

Selection and Analysis of Key Articles

Because these key articles formed the basis of our analysis, we devoted considerable thought to their selection. We realized that bias in selecting them could invalidate our study and that their careful review by consultants was essential. At the same time, experience with pilot studies showed us that scientists are rarely unanimous in voting that Jones's discovery is more important than Smith's. Sometimes this is because of justified differences in judgment; sometimes it is because there is no one article that can be singled out from many in a steady advance with many equal contributors. We solved this problem for the purposes of this study (though not for election of individual scientists to a "Hall of Fame") by first selecting key articles in 42 of our tables and then sending the same tables (with no clue to our choices) to reviewers for their independent selection. We then analyzed the articles that we had selected to determine the goal of the investigators and repeated the same process for the articles selected by our reviewers. Although there was not complete agreement on the selection of individual key articles, there was almost exact agreement on the type of articles selected. Thus the percentage of key articles reporting research that was not clinically oriented was almost identical in their selections and in ours (Table 4). Because our interest was in determining the type of research reported in key articles (for example, clinically oriented research or that which was not clinically oriented) rather than in identifying specific scientists and their reports, we believe that the agreement on type, based on a sample of more than 50 percent of our key articles, justifies our extending it to the whole group (*5*).

Once the key articles were selected, we re-read and analyzed each article to determine the answers to the following questions. (i) How many key studies were clinically oriented? How many were not directed toward the solution of a clinical problem? (ii) How many key articles reported basic research? Other kinds of research? Development or engineering?

Was the Key Research Clinically Oriented?

To eliminate uncertainty about our definitions, in this section we avoid classifying research as clinical investigation, basic research, fundamental studies, directed or undirected research, or targeted or nontargeted research. Instead, we use only two terms; (i) clinically oriented research, and (ii) research that was not clinically oriented.

We define research as clinically oriented, even if it was performed entirely on animals, tissues, cells, or subcellular particles, if the author mentions even briefly an interest in diagnosis, treatment, or prevention of a clinical disorder or in explaining the basic mechanisms of a sign or symptom of the disease itself. Thus the Nobel Prize-winning research of Enders, Weller, and Robbins on extraneural culture of poliovirus in vitro was classified as clinically oriented because the team expressed an interest in multiplication of poliovirus outside the nervous system (for example, in the patient's gastrointestinal tract).

We define research as not clinically oriented if the authors neither state nor suggest any direct or indirect bearing that their research might have on a clini-

Table 4. Goal of authors of key articles as selected by reviewers and by us from the same 42 tables.

Key articles selected by	Number of articles	Goal was not clinically oriented	Goal was clinically oriented	Percent of total not clinically oriented
Reviewers	494*	189*	305*	38.3
Us	267	101	166	37.8

*Total number of key articles selected by reviewers is higher than number selected by us because (i) the reviewers on the average selected 8.4 key articles per table and we selected on the average only 6.7 for these 42 tables; and (ii) we sent some tables to more than one reviewer.

cal disorder of humans, even though their work later helped to clarify some aspect of it. An article can be classified as not clinically oriented even if the research is done on a human (for example, Oliver's administration of an adrenal extract, later known as epinephrine, to his son in 1895 to see whether it would narrow the diameter of his radial artery).

Each article was classified as one or the other without consideration of earlier or later work of the same investigator and without being influenced by later stories (written or verbal) of "Why I did my research." The results of classifying 529 key articles into these two categories are shown in Table 5.

These data strongly support our contention that those concerned with preserving or changing national biomedical science policy should disregard anecdotal "evidence" no matter how convincingly the case is presented. Table 5 shows that someone looking for evidence to defend any position on the support of research can get it by choosing the right clinical advance as his example or his for-instance. If one picks vascular surgery or antibiotics or poliomyelitis, one can "prove" that clinically oriented research deserves major support; if one selects hypertension or oral diuretics or new diagnostic tests, one can "prove" that research that is not clinically oriented deserves major support.

The most important figure in Table 5 is that, for cardiovascular and pulmonary advances as a whole, 41 percent of all work judged to be essential or crucial for later clinical advances was not clinically

Table 5. Goal of authors of 529 key articles that later were judged to be essential for a clinical advance.

Clinical advance	Clinically oriented	Not clinically oriented	Total	Percent of total not clinically oriented
Cardiac surgery	53	35	88	39.8
Vascular surgery	40	8	48	16.7
Hypertension	35	44	79	55.7
Coronary insufficiency	44	21	65	32.3
Cardiac resuscitation	24	16	40	40.0
Oral diuretics	19	24	43	55.8
Intensive care	*	*	*	*
Antibiotics	40	13	53	24.5
New diagnostic methods	41	53	94	56.4
Poliomyelitis	16	3	19	15.8
Total	312	217	529	41.0

*A key article is assigned to only one advance even though it may have been essential to more than one. Because practically every key article in intensive care was also essential to other advances, these articles were assigned elsewhere (for example, to cardiac or vascular surgery, coronary insufficiency, resuscitation, or antibiotics).

oriented at the time of the research; 41 percent of the investigators, when they did their work, expressed no interest in a clinical problem—their goal was knowledge for the sake of knowledge. These data indicate clearly that planning for future clinical advances must include generous support for innovative and imaginative research that bears no discernible relation to a clinical problem at the time of peer review. Because of many unknown factors (for example, ratio of clinical as compared to nonclinical scientists who do not produce key articles to those who do; relative costs of supporting one type of scientist versus the other), we cannot translate "generous support" into a percentage of NIH's budget for extramural programs. Nor can we transfer conclusions from a study of cardiovascular and pulmonary research to other research fields, such as cancer research. But the conclusion seems inescapable that programs to identify and then to provide long-term support for creative individuals or groups (judged more likely than others to produce key research) should be expanded.

Was the Key Research Basic or Not?

Earlier, we avoided using the term basic research. We must now use it and define what we mean by it. We classify research as basic when the investigator, in addition to observing, describing, or measuring, attempts to determine the mechanisms responsible for the observed effects; with our definition, basic research can be on healthy or sick people, on animals, tissues, cells, or subcellular components. Our definition differs from the layman's (and some scientists') concept that research is more and more basic when the unit investigated is smaller and smaller; further, it allows that work on small units, such as cells, need not be basic if it is purely descriptive. It steers clear of whether the research was initiated by the investigator or by a commission, whether it was undirected or directed, whether supported by grant or by contract, because who initiated, directed, or supported the research has nothing to do with whether it is basic.

We analyzed each key article to determine how each investigator carried out his research and put each article in one or more of six categories.

1) Basic research unrelated to the solution of a clinical problem.

2) Basic research related to the solution of a clinical problem.

The clinical relationship was obvious when the investigator studied basic mechanisms of disease in patients; when it was not obvious, we depended on the investigator's statement, no matter how brief, that he initiated his research to gain further insights to the diagnosis, treatment, or prevention of human disease.

Two examples will clarify the difference between categories 1 and 2. When Landsteiner discovered human blood groups in 1900 he was investigating a basic problem in immunology and had no thought of the importance of his discovery to the transfusion of blood; this was clearly basic research unrelated at the time to the solution of a clinical problem (category 1). When Landsteiner, in 1909, found that a nonbacterial material (a virus) caused poliomyelitis in monkeys, this again was basic research but, since it was clearly related to a clinical problem, it fits category 2.

3) Studies not concerned with basic biological, chemical, or physical mechanisms.

These include purely descriptive studies (for example, description of a new disease, such as Stokes-Adams disease, without an investigation of the mechanism); an important observation that initially required no research (inhalation of ether causes anesthesia); a new procedure that required no research (cardiac catheterization); a new operation on humans that first required only perfecting surgical techniques in animals; and clinical tests of a new diuretic, antibiotic, or antihypertensive drug in humans without measurements designed to determine its mechanism of action.

4) Review and critical analysis of published work and synthesis of new concepts (without new experimental data).

5) Developmental work or engineering to create, improve, or perfect apparatus or a technique for research use.

6) Developmental work or engineering to create, improve, or perfect apparatus or a technique for use in diagnosis or care of patients.

The difference between categories 5 and 6 can be clarified by an example. Bayliss and Müller developed a roller-pump in 1929 to solve a problem in basic cardiac physiology; we classify this under category 5 even though later, as the DeBakey pump, it had widespread clinical use. The Drinker respirator (iron lung), developed for clinical use, we classify under category 6.

The results of classifying 529 key articles into these six categories are shown in Table 6. Note that of 567 entries, 209 are in category 1 and 141 in category 2; the total of studies in basic research, either unrelated or related to a clinical problem, was 350, or 61.7 percent of the total number of entries. Other types of clinically oriented studies (some inevitable once the basic research was done) (*4*) accounted for 21.2 percent of the total; development and engineering (much of it inevitable once the basic research was done) (*4*) accounted for15.3 percent; synthesis accounted for less than 2 percent. Basic research therefore was responsible for almost three times as many key articles as other types of research and almost twice as many as nonbasic research and development combined.

Objectivity of Our Study

Research on the process of discovery is unusually difficult in that the data come from judgments and decisions and not from physical measurements. Further, no matter how many consultants participate in the judgments and no matter how distinguished each is, to be a consultant each must be an expert in his field of knowledge (we cannot ask clergy, lawyers, or ethicists to determine which were the key advances leading to the prevention of poliomyelitis), and as such, each is likely to have some bias.

In the case of our study, its objectivity is strengthened by the fact that, although the data and conclusions emphasize the importance of nonclinically oriented research and of basic research for clinical advance, only 26 percent of our consultants and only 24 percent of advisers on key articles were basic scientists (*3, 5*).

In the long run, data and conclusions from any single study should stand, fall, or be modified not by anecdotes or gut reactions, but by confirmation or refutation by better studies with improved design and more objective methods. We believe that a $2 billion industry might well put more of its annual budget into research on improving its main product, which in this case is discovery and its application.

Summary and Conclusions

There has been much expert testimony before congressional committees and much national debate on the relative value of targeted in contrast to nontargeted and of applied in contrast to basic biomedical research. Most of it has been based on anecdotal evidence and little or none on an objective analysis of research in broad fields of medicine and surgery. This is understandable because for-instances are easy to come by, whereas research on research is unusually difficult and time consuming. Because we believe that national biomedical science policy should be based on research on the nature of discovery and its application, we have devoted several years to analyzing how and why lifesaving advances have come about in cardiovascu-

Table 6. Types of research reported in 529 key articles.

Type	Basic: not clinically oriented	Basic: clinically oriented	Not basic	Review and synthesis	Development: research	Development: clinical	Total
Cardiac surgery	34	23	19	0	3	11	90
Vascular surgery	9	7	14	3	0	21	54
Hypertension	42	16	21	2	0	0	81
Coronary insufficiency	21	20	22	1	1	3	68
Cardiac resuscitation	16	11	9	0	0	6	42
Oral diuretics	23	13	6	1	0	0	43
Intensive care	*	*	*	*	*	*	*
Antibiotics	12	18	21	1	0	2	54
New diagnostic methods	49	21	5	2	17	22	116
Poliomyelitis	3	12	3	0	1	0	19
Total	209	141	120	10	22	65	567†
Percent of total	36.8 //	24.9 //	21.2	1.8	3.9	11.4	

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*Because practically every key article in intensive care was also essential to other advances, these articles were assigned elsewhere (for example, to cardiac or vascular surgery, coronary insufficiency, resuscitation, or antibiotics). †The total number of entries in the six categories (567) exceeds the total in Table 5 (529) by 38 entries. This is because some key articles fit into more than one category here, particularly when articles reporting development of new apparatus also reported research using it; no article in Table 5 was classified more than once.

lar and pulmonary diseases. The advances that we studied were open-heart surgery, blood vessel surgery, treatment of hypertension, management of coronary artery disease, prevention of poliomyelitis, chemotherapy of tuberculosis and acute rheumatic fever, cardiac resuscitation and cardiac pacemakers, oral diuretics (for treatment of high blood pressure or of congestive heart failure), intensive care units, and new diagnostic methods. We screened more than 4000 scientific articles published in these fields, selected 2500 of these for further consideration, and then analyzed 529 of those that we (and 140 consultants) considered to be essential for the clinical advances.

Our analysis showed the following. (i) Of 529 key articles, 41 percent of all work judged to be essential for later clinical advance was not clinically oriented at the time it was done; the scientists responsible for these key articles sought knowledge for the sake of knowledge. (ii) Of the 529 articles, 61.7 percent described basic research (defined as research to determine mechanisms by which living organisms—including humans—function, or mechanisms by which drugs act); 21.2 percent reported other types of research; 15.3 percent were concerned with development of new apparatus, techniques, operations, or procedures; and 1.8 percent were review articles or reported synthesis of the data of others. Our data show that clinical advance requires different types of research and development and not one to the exclusion of another. Thus the problem is not either-or, but a question of how much support to one type and how much to another. Our data compel us to conclude (i) that a generous portion of the nation's biomedical research dollars should be used to identify and then to provide long-term support for creative scientists whose main goal is to learn how living organisms function, without regard to the immediate relation of their research to specific human diseases, and (ii) that basic research, as we have defined it, pays off in terms of key discoveries almost twice as handsomely as other types of research and development combined.

We believe that much more research needs to be done on the nature of research and its application so that data from objective studies can be applied to all aspects of biomedical research. Because the very nature of research on research, particularly if it is prospective rather than retrospective, requires long periods of time, we recommend that an independent, highly competent group be established with ample, long-term support to conduct and support retrospective and prospective research on the nature of scientific discovery, to analyze the causes of long and short lags between discovery and clinical application and to suggest and test means of decreasing long lags, and to evaluate present and proposed mechanisms for the support of biomedical research and development.

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3. Of these, 70 were clinicians, 37 were basic medical scientists, and 33 were engineers, science administrators (in industry, government, or universities), or science writers.
4. Some consultants did not designate such contributions as key articles. We did, however, because we knew of a number of instances in which the final step was "inevitable" but no one seemed willing to take it (for example, vascular surgery was inevitable by 1910 but was not applied until 1939).
5. Bias could also enter into our selection of reviewers of tables. Thirty-two reviewers were physicians, surgeons, or medical or surgical specialists; 10 were basic medical scientists. All were highly knowledgeable in the field that they reviewed.
6. Supported by contract 1-HO-1-2327 from the National Heart and Lung Institute and grants from the Commonwealth Fund and The Burroughs Wellcome Fund.

Mr. HARPER. Thank you.

We appreciate deeply the past support of the subcommittee for basic biological and biomedical research, but we are highly conscious and deeply concerned about the devastating impact that the enormous budget deficit and the Gramm-Rudman-Hollings law could have on basic research, and in particular the funding of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

I think in the effort to achieve a balanced budget, it is important to recognize that basic biological and biomedical research contributes to the health and well-being of all Americans, in fact to all of mankind. Basic biomedical research is part of a humanitarian effort to relieve human suffering, but it is not simply a humanitarian effort. Healthy Americans are our major natural resource.

The development of all of our other resources depends upon having a healthy population. Healthy people are also crucial as part of our national defense. In fact, at the outbreak of World War II, plans were immediately made to ensure healthful diets for the Armed Forces and for all Americans.

It is also important, I think, to recognize the source of knowledge for major clinical contributions and advances. Doctors Kamerow and Drips identified 10 major clinical advances between 1946 and 1976. For these 10 advances, they identified 137 bodies of knowledge that were required, 2,500 specific scientific contributions, and they suggested that they had not by any means identified all of them.

They concluded that the idea that each discovery is the contribution of one individual was a myth and that it was clear from these studies that scientists who preceded and those who followed were essential to each discovery and its subsequent development.

They also found that 40 percent of the crucial contributions were made by scientists who had expressed no interest originally in the clinical problem to which they contributed. These findings emphasized the importance of supporting innovative and imaginative research that may bear no obvious relationship to a specific clinical problem or disease entity.

These contributions arose from the creativity of a vast number of scientists and the willingness of society to support their basic research.

The President's budget for fiscal year 1987 represents a decrease of more than $400 million from the 1986 figure. The NIH would support only 5,104 new and competing grants, which would be down from the 6,100 in fiscal 1986.

The Alcohol, Drug Abuse, and Mental Health Administration research budget would be down by 5 percent, and the investigator-initiated new grants probably by 10 percent. These proposed cuts are deeply disturbing because the momentum in acquisition of new knowledge is lost when Federal funding declines, particularly if it declines unexpectedly.

Also, our bright and inquisitive and even established investigators perceived that a career in federally sponsored basic biological research may be unreasonably precarious. This drives not only trained researchers from the field but discourages promising young people from entering it, people we can least afford to lose.

So we would recommend that the funding level, along with the ad hoc group of 150 different societies concerned with health research, be of a level of $465 million, which would allow the ADAMHA research budget to support expanded numbers of competing grants, and that the NIH budget be at the level of $3.4 billion to $3.6 billion, which was also recommended by this ad hoc group, and this level would be sufficient to support 6,100 research grants which the committee supported last year and which we applaud strongly.

In conclusion, I would like to state that as working scientists, we assure you of our support. Particularly the individual investigator-initiated research grant is essential. It is essential to provide knowledge needed for the major medical and clinical advances, and we urge the committee to continue its enlightened investment in the health of our people.

Senator PROXMIRE. Thank you very, very much, Mr. Harper.

A few months ago I introduced legislation authorizing a modest amount for studies of the outcomes of procedures that have wide variations in use from region to region in the United States. We found that in some States, for instance, the number of prostatectomies and the number of hysterectomies varied enormously from region to region. In some communities, 15 or 20 percent of the men who reach the age of 85 had undergone prostatectomies while in other cases 50 percent of the men had undergone this procedure. With no outcome studies, we have no notion of whether, on the basis of these enormous differences, it is better to proceed with surgery or use some other kind of treatment.

The idea is that if a procedure is used at widely different rates in different areas, we should know more about how effective it is. Do you think that we are doing enough in this area?

Mr. HARPER. This is one of the points that was made by the people who have looked at the innovative developments in clinical medicine, and their emphasis was on one of the important developments being diagnostic tools, the ability to diagnose accurately, and that this was a major advance that was necessary before open heart surgery could be successful.

I think this should apply generally for procedures of this type. There is a need for substantial knowledge of accurate diagnosis.

Senator PROXMIRE. I appreciate that. We have felt that a very, very small proportion, a tiny fraction of 1 percent, of the Medicare budget would be able to give us a great deal of information we don't have now in the type of case I have cited, and it should improve the outlook for survival as well as reduce costs.

Mr. HARPER. I was interested in that article, and I would like to submit a copy for the proceedings of the committee.

Senator PROXMIRE. I appreciate that very much.

Mr. HARPER. They emphasize the tremendous number of developments, particularly for new surgical procedures that were essential for success, and this included diagnostic procedures, it included technical procedures, and some engineering procedures, even, and I thought it was extremely useful.

Senator PROXMIRE. Thank you very much.

I am going to the floor in a few minutes to demonstrate to the Congress the importance of Wisconsin cheese. That is why I have this cheese with me. And of course, cheese will make you look younger, feel better, live longer, and live a lot more happily.

It is great to have you here.

Mr. HARPER. Thank you, sir.

STATEMENT OF WILLIAM K. RIKER, PRESIDENT, AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS

Senator PROXMIRE. Our next witness is Dr. William Riker. Dr. Riker is the president of the American Society for Pharmacology and Experimental Therapeutics.

Dr. RIKER. Good morning, Senator Proxmire and members of the committee. Thank you very much for the opportunity to appear before you today to discuss funding for biomedical and biological research.

I must say that Oregon also has cheese that is quite good, and you must try that.

Senator PROXMIRE. It also has the chairman of the committee, who is the big cheese on this committee. [Laughter.]

Dr. RIKER. We just spent 15 minutes with Senator Hatfield.

Senator PROXMIRE. Incidentally, we produce 40 percent of all the cheese in the country, so we do pretty well.

Dr. RIKER. Very good.

I am William Riker, a physician, a working scientist, and professor and chairman of the Department of Pharmacology at the School of Medicine of the Oregon Health Sciences University. As you said, I am here today as president of the American Society for Pharmacology and Experimental Therapeutics.

The pharmacology society is one of the constituent societies of the Federation of American Societies for Experimental Biology, and it is also the national affiliation of pharmacologists working in universities, the pharmaceutical industry and Government, and our major purpose, of course, is to discover and disseminate new information about drugs, from the most basic levels of research to new drug discovery to clinical study of drugs in patients.

Senator PROXMIRE. Dr. Riker, I am going to have to interrupt you for 1 minute. Senator Andrews has arrived. He is chairing the committee and I am going to have to go to the Senate floor. As I explained, this is to show to the vast TV audience we now have in the Senate the importance of Wisconsin cheese. The myth is that people are eating less of it. Actually, they are eating about 10 percent more than they were last year.

Senator ANDREWS [presiding]. I thought you brought them here to pass around samples, Bill.

Senator PROXMIRE. Well, I will keep that in mind. I would be delighted to pass around samples.

Senator ANDREWS. Sharp cheddar, please, old friend.

Senator PROXMIRE. These are a little big, though, you know.

Senator ANDREWS. Well, I don't know about that. We can whittle away at them.

Senator PROXMIRE. I am sure you could.

Senator ANDREWS. Doctor.

Dr. RIKER. Senator Andrews, thank you, and may I have equal time? [Laughter.]

Senator PROXMIRE. This won't be taken out of your time. [Laughter.]

Dr. RIKER. I was explaining to Senator Proxmire and the members of the committee that the pharmacologists work right at the interface between the laboratory bench and the bedside, and our goal, of course, is to prevent and relieve sickness and disease, not just for 1987 but for the 21st century and beyond.

For that reason, we are vitally concerned about the appropriation bill that funds the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration. We believe that if the administration succeeds in reducing the number of new and competing grants in 1987 to 5,100 and perpetuates that number through 1991, we could approach the 21st century with at least 3,000 fewer research laboratories at work, and an even greater number of essential research discoveries lost forever.

Therefore, we urge you, Mr. Chairman and the members of this committee to ensure that the appropriation level for NIH in fiscal year 1987 is sufficient to fund at least 6,100 new and competing grants, to increase the number of research trainees, and also to ensure that funding level for ADAMHA is also sufficient to allow for an expanded number of new and competing grants and increased numbers of trainees.

This committee and you, Mr. Chairman, have been outstanding in your support of biomedical and biological research in the past. We are especially pleased at the recent addition of $500 million to the NIH budget by the Senate budget resolution. We deeply appreciate that commitment, and we hope that there will be an opportunity with flexibility in the budget to increase that level beyond that.

I think all of the members of this committee are highly knowledgeable about the nature of biological research, and that the big breakthroughs are unexpected and would not have occurred without the hundreds, even thousands of essential but unheralded discoveries that pave the way. That certainly is true for penicillin, as it was for Crick and Watson's deciphering the genetic code.

So that the administration's plan to reduce the number of new and competing grants will inevitably reduce those supporting discoveries and the breakthroughs, and those breakthroughs have come about really because of the long and successful history of NIH, which included a funding rate of grants of approximately 50 percent.

The administration's plan would be to reduce that number to a funding rate of 27 percent, a step that would not only threaten one of our remaining bastions of world leadership, that of biomedical research, but would also deprive the Nation of significant future health benefits.

PREPARED STATEMENT

Mr. Chairman, I thank you very much for the time available to me today, and I will be happy to answer any questions you may have.

[The statement follows:]

STATEMENT OF WILLIAM K. RIKER

Mr. Chairman, members of the subcommittee, thank you for this opportunity to appear before you today to discuss funding for biological and biomedical research. I am William Riker. By training I am a physician and am Professor and Chairman of the Department of Pharmacology, School of Medicine, The Oregon Health Sciences University. I am also President of the American Society for Pharmacology and Experimental Therapeutics (ASPET), and it is in this capacity that I appear before you today.

ASPET is one of the seven constituent societies of the Federation of American Societies for Experimental Biology (FASEB), which represents 28,000 scientific researchers in the biological and biomedical sciences. ASPET's purpose is to promote pharmacological knowledge and its application and to conduct research with the ultimate goal of preventing and relieving sickness and disease. We are working scientists. For that reason, the appropriations bill that funds the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration is of primary importance to us. We are deeply disappointed by the President's fiscal 1987 request for these agencies.

You, Mr. Chairman, and this subcommittee have been exemplary in your support of basic biological research and we appreciate this commitment. We only hope these efforts can continue in the face of the Gramm-Rudman-Hollings mandate to balance the federal budget by 1991. As I am sure you are aware, Gramm-Rudman-Hollings could have a devastating impact on relatively unprotected basic research funding if it is implemented in fiscal 1987. Congress must recognize, since the Administration clearly does not, that basic biological research has a legitimate claim to a reasonable portion of scarce fiscal 1987 federal dollars. Basic research is a unique and humanitarian effort, undertaken for the benefit of all Americans, and, it can be argued, of all mankind. It is heavily dependent on federal support because its primary objective is disease treatment and cure and a fuller understanding of the complex processes of life, not profit. However, when viewed as an investment, it pays enormous cost-saving and life-saving dividends over the long-term. American scientists have been able to achieve international stature in the area of biological and biomedical research because of a long-term commitment by the federal government, articulated and insisted upon most powerfully by Congress and particularly by this subcommittee.

In fiscal 1987, however, the Administration would provide only $4.9 billion for NIH, a decrease of more than $400 million from the fiscal 1986 appropriation. Under this plan, NIH would support only 5,104 new and competing grants, down from 6,100 in fiscal 1986. The number of research centers would drop from the fiscal 1986 level of 550 to 523 and the number of trainees supported would fall from 9,947 to 9,250. For Alcohol, Drug Abuse and Mental Health Administration research, the Administration is requesting $318.9 million, a five percent decrease below the fiscal 1986 research funding level of $335.6 million. Investigator-initiated new and competing grants would drop from 505 in fiscal 1986 to 448 in fiscal 1987. ADAMHA training programs would be cut back from the $41 million fiscal 1986 enacted level to only $18.5 million in fiscal 1987.

These proposed cuts are deeply disturbing. The consequences of reduced funding levels for NIH and ADAMHA in fiscal 1987 cannot be summarized in terms of fewer projects supported and fewer people trained. The cost of research forgone now cannot be measured by the number of dollars saved and put toward a smaller deficit. The consequences must be weighed in terms of human suffering not alleviated and the incalculable long-term costs of lost scientific opportunity.

The progress of scientific knowledge and the momentum of discoveries also depends on our ability to recruit and train the next generation of scientists. The Administration budgets for NIH and ADAMHA tell our bright, inquisitive undergraduate and graduate students, our young, promising scientists and our established investigators that a career in federally-sponsored basic biological research may be unreasonably precarious. This instability not only drives trained researchers from the field but, more worrisomely, discourages promising young people from entering it. This loss of people cannot be easily recouped.

We note a recent National Science Foundation survey which shows that federally-funded research grants have become an increasingly important mechanism for supporting the training of pre-doctoral researchers. You should be aware of this connection between the research grant line item and the research training line item--the two complement one another and are dependent on one another for success.

We join with FASEB and the Ad Hoc Group for Medical Research Funding, a coalition of more than 150 organizations, in recommending a fiscal 1987 funding level for NIH of $6.079 billion. This funding level represents an increase of about $86 million or 1.4 percent over a current services budget. Our recommendation would restore the cuts made by the Administration budget request in a number of areas, including biomedical research support grants, and would continue most NIH programs at their fiscal 1986 level of operation. In addition, the Ad Hoc Group proposal would provide funds sufficient to raise the number of research trainees to the level recommended by the National Academy of Sciences, to upgrade and renovate primate centers and other facilities, to strengthen support for clinical trials through general clinical research centers and increase the number of specialized and comprehensive research centers.

For NIH competing and non-competing research project grants, the Ad Hoc Group recommends a current services dollar level for full funding at study section recommended amounts--a total of between $3.4 billion and $3.6 billion. This level should be sufficient to fund 6,100 new and competing NIH grants in fiscal 1987. ASPET believes Congress acted wisely in increasing the number of new and competing grants to 6,100 in fiscal 1986 and recommends that at least the 6,100-grant level be maintained in the coming fiscal year and that this number be cited by the subcommittee.

The investigator-initiated research project grant continues to be the keystone of the NIH and ADAMHA efforts because it explores questions at the cutting edge of research, offering the greatest hope for progress against disease. The number of new and competing grants and the depth of training support are key indicators of the health of these research programs. If Congress fails to make the grant and training levels a clear priority, OMB has shown it will not hesitate to reduce NIH and ADAMHA support in defiance of non-binding congressional intent, a serious setback for research.

For the Alcohol, Drug Abuse and Mental Health Administration we join with the Ad Hoc Group in recommending a research funding level of $465 million. This proposal is consistent with the Institute of Medicine recommendation that ADAMHA's research budget be doubled from 1986 to 1991. This increase would allow for an expanded level of new and competing grants, growth in Research Centers and Research Scientist Development Awards with a focus on young investigators, an increased number of trainees, and badly needed renovation of facilities and equipment.

We urge this subcommittee to provide funding levels for NIH and ADAMHA that allow us to maintain the momentum of biological, biomedical and behavioral research. As working scientists, we assure you that your support, particularly in the areas of the individual investigator-initiated research grant and training, is not only essential to our work, but the reason we have been so successful in our endeavors.

I would be happy to answer any questions you may have.

Senator ANDREWS. Thank you very much, doctor, for an excellent statement, and I also appreciate, as does our chairman, Senator Weicker, the kind words you had to say about the Weicker-Andrews amendment to the budget resolution. We are glad that it went into place.

We feel this is more an investment than a spending program, and if I ever forgot that, given the great leadership of our School of Pharmacy at North Dakota State University, our people out there would remind me, as you know. They are very aggressive and very competent in that field. And even if I forgot that, I will conclude by pointing out that my grandparents came to Dakota Territory 3 years after a fellow by the name of Custer got shot up in a little disagreement with the Indians, and they came to the little town of Mapleton, ND, to set up a pharmacy, and that was more than 100 years ago, more than we were a State. So I understand wherein you are speaking.

Today it is a far more sophisticated business. The investment in better knowledge, pharmacological methods can only help future generations of Americans, and we are glad to have you here.

Thanks very much, doctor.

Dr. RIKER. Thank you very much.

STATEMENT OF WILLIAM C. DEMENT, M.D., PRESIDENT, ASSOCIATION OF SLEEP DISORDERS

Senator ANDREWS. Our next witness is Dr. William Dement, president of the Association of Sleep Disorders. Doctor, let me assure you, as I am sure other Senators have other witnesses, that your full statement will appear in the record as though uttered every word, and you can summarize in any way you wish. The light limits you to 5 minutes for the benefit of the other witnesses, and we get more chance for questions if the light hasn't turned to red before you stop your testimony.

Dr. DEMENT. I will do my best, Senator. This is very precious time.

My credentials are a lifetime working in sleep research and clinical sleep disorders. I am also president of the Clinical Sleep Society.

The most important thing I want to tell you is that when you fall asleep, your brain is just as active as it is when you are awake, and most people think of it as a brain turned off. It isn't at all. It is more active during sleep than when awake, and we need to know what it is doing.

When I started, in the 1950's, I was the first person to study human sleep continuously through the night. And in 1970 we founded the first sleep disorders center to take care of the sleeping patient. In 1970, you could say that the practice of medicine ended when the patient fell asleep. Nobody knew anything about what went on during sleep. Since that time, we now have 1,000 places where we study sleep disorders and we need to know more about the sleeping brain.

I appreciate very much the help of this committee. Last year you asked the Director of NIH to give a report on the coordination and integration of sleep research and he did. And it is a laudable summary of laudable work, but by and large the work is peripheral because of the missions of the Institute. So it would be sleep in cancer patients, which is laudable, sleep in Alzheimer's disease, sleep in heart disease. But the fundamental questions of the sleeping brain are still unaddressed; what is it doing, how does it work, what is going on in the sleeping brain? And above all, what goes wrong at night?

One thing that we know is that there are much greater tendencies to die during sleep than during wake. Sleep puts us at risk. The sleeping, working, active brain is failing at night in millions of Americans. Twenty-five million Americans stop breathing when they fall asleep. So we have all this work to do on these fundamental issues.

And I am not here to ask for money. What we want is a voice. That is all of us who have worked for 25 years to establish the field, to do the research, to publish thousands of papers. We are taking care of patients all over the United States. We just want to have a voice in the program and policy of NIH.

PREPARED STATEMENT

If we can bring our expertise to bear, we think we can remedy these problems.

[The statement follows:]

STATEMENT OF WILLIAM C. DEMENT

Mr. Chairman, distinguished and Honorable Senators, ladies and gentlemen, I am Dr. William Dement. I am a professor in the Department of Psychiatry and Behavioral Sciences at Stanford University where I direct the nationally renowned Sleep Disorders Program. I have devoted my entire professional career to basic and clinical sleep disorders. When I began my work in 1952, I was the only scientist in America who was staying up all night to observe and define the course of nocturnal events in human sleep.

Today I have more than 1,000 colleagues, perhaps 2,000, who are practicing one of America's newest clinical subspecialties, sleep disorders medicine. A professional organization has come into being only in the past few years and is comprised of the Association of Sleep Disorders Centers, the Clinical Sleep Society, the Sleep Research Society, and the Association of Polysomnographic Technologists. It is called the Association of Professional Sleep Societies and will soon have its first meeting in Columbus during the week of June 15-21.

Honorable Senators, at this very moment, as I talk to you, some three billion people on the other side of the earth are sleeping or trying to sleep and hundreds are dying because they are sleeping. As the earth turns, another two billion will go through the valley of the shadow of sleep and death.

In order to discuss the issues, I must make a few statements about the true nature of sleep. It is quite likely that your beliefs about sleep are exactly the opposite of what is known to be true. The essentials can be summarized in three fundamental prinicples of the sleeping brain.

The first principle is that the sleeping brain is more active than the waking brain. Through we experience sleep as a "time out," this is completely misleading. The overt bodily quiescence of sleep is completely misleading. The sleeping brain is just as active as the waking brain and is often more active. The brain is doing.

The second principle is that the sleeping brain is an entirely different brain from the working brain. One way to formulate this principle is to think of the brain as a marvelous computer with two totally different operating systems.

The third principle is that sleep has many purposes. One obvious purpose is to maintain the vital processes of breathing, heartbeat, and the flow of oxygenated blood while we sleep. Another simple task is the biochemical work that is required for us to remain fully awake in the succeeding day. This work is an active biochemical task and involves processes which take the whole night and must be completed if we are to sustain optimal alertness throughout the subsequent day.

Other purposes of sleep are less understood. They have something to do with vitality and longevity. We know that we cannot live without sleep. Deprived of all sleep organisms deteriorate and die.

The most important message that has to be repeated over and over is that sleep is an active, purposefull, very complex process. It is delicate, exquisitely orchestrated process which can easily become abnormal. In the past decade, clinical practitioners have pulled back the curtain of the night to reveal what is really happening to human sleep.

Something is going wrong with the activity of the sleeping brain in more than a hundred million Americans. What are examples of the illnesses of the sleeping brain? Sudden infant death syndrome, narcolepsy, sleep apnea syndrome, insomnia, stroke and epilepsy, the aging of sleep. Drugs and alcohol impair sleep, abnormal work schedules and jet travel impair sleep and sudden unexpected death in adults peaks during the night from about 6:00 p.m. to 8:00 a.m. and the single best predictor of life expectancy established through highly respected epidemiological studies is how much sleep a person gets at night. The American public does not even know the simple facts of sleep. How much sleep do you need to be awake the next day? We have established that college students need nine-and-a-half hours of sleep. They habitually get less than seven are are chronically sleepy all the time. Adults are the same. Older citizens are particularly plagued.

Last year my friend and colleague, Dr. Merrill Mitler, testified before this committee and the result was report language, to wit, "The committee has heard testimony concerning the sleeping disorders of sleep exacerbated diseases that millions of Americans suffer each night. Some of the disorders described included insomnia, narcolepsy, sleep apnea, respiratory disorders, epilepsy, nocturnal nightmares, and night terrors. The committee believes that better coordination would provide a continuity to the research efforts would eventually provide answers to the many questions regarding sleep disorders. Therefore, the committee would like the Director of NIH to inform the committee prior to the fiscal year 1987 budget hearing regarding steps the NIH should take to accomplish a better degree of continuity and coordination of sleep disorders research."

This report, which you have seen, is the result. We hope the committee will continue to follow up on the results of this report and recognize possibly that NIH could further improve their coordination of sleep research by enhancing their relationship with recognized experts in the field.

Although everyone in the world sleeps, and there are more than 10,000 neuroscientists in the United States, I cannot count ten scientists in the entire United States who are saying, "I want to devote my life to researching mysteries of the sleeping brain." Our inability to provide careers for young basic scientists to work on the problems of the sleeping brain has become a near catastrophe for the field. Academic/research careers in basic sleep research must be fostered.

Generally speaking, the biggest obstacle for basic and clinical sleep research has been lack of "designated responsibility" within the Department of Health and Human Services (HHS). An admirable step forward has been taken. More can be done. Research in sleep disorders cuts across all medical disciplines. No established dicipline or institute has been willing to take complete responsibility for the sleeping brain.

Sleep Disorders is a multidisciplinary field and the hardest field for NIH to maintain funding for because there is no established program; therefore people are leaving the field. People are trying to make sleep fit in established fields (epilepsy and sleep; COPD and sleep) rather than in basic.

In view of all the facts and considerations stated above, it is clear that the well-being of the human race -- of all Americans -- during sleep should rank among the very top of our health concerns.

I am here to remind you that we must increase our level of basic research on the sleeping brain. We must understand its workings and it illnesses. With as much urgency as possible, I say that the mysteries of the sleeping brain are worthy as the mysteries of the atom, the gene, and yes, the waking brain. Federal policy must recognize the health and safety issues related to sleep pathology, and research funding must relect the financial and social impact that sleep pathology has on our society. **WHAT CAN AND SHOULD BE DONE**?

The first step is recognition and acceptance that millions of Americans have serious sleep disorders and are seeking relief. Death and disability occur in millions of our citizens as a direct result of sleep disorders. We must also recognize that the federal involvement in this area is essentially zero. Of the billions and billions of dollars expended for health, 99.9 percent go to promote the waking half of our existence. We must elevate the sleeping brain and its many illnesses to a status equal to the waking brain.

The peripheral interests are fosted by the institutes, e.g., sleep and epilepsy, sleep and depression; but core questions do not receive the attention they deserve. It is quite possible that some of the funds allocated this committee could be rechanneled into programs which foster an understanding of the one totally unexplored continent that remains. What is going on in the sleeping brain?

Here are examples of specific research questions which should be pursued.

QUESTION 1: WHICH PATIENTS ARE AT RISK FOR DEATH OR DISABILITY FROM HEART ATTACK, STROKE AND SEIZURE WHEN THEY SLEEP?

Major medical problems leading to death or disability arise during the night. These events seem to occur between midnight and 6 a.m. Heart and breathing problems during sleep are usually involved.

People with the clincial signs of such cardiopulmonary problems during sleep are demanding treatment and physicians are treating. My colleagues in this country see about 500 new patients each week with these abnormalities. Mecial costs of diagnosis and the initial surgical and medical treatments for these particular sleep disorders average about $5,000 per patient -- or $130 million annually.

There is no federally funded research on the long-term efficacy of any of the surgical and medical treatments now used.

QUESTION 2: WHICH SLEEPING PILLS ARE SAFE FOR PATIENTS WITH CHRONIC INSOMNIA?

Over $200 million is spent on sleeping pills alone each year. Most prescriptions are given to chronic users. But the long-term safety of these drugs is unknown.

The Institute of Medicine has recently rcommended that more research on sleeping pill safety should be done.

QUESTION 3: WHICH PATIENTS SHOULD NOT DRIVE MOTOR VEHICLES, PILOT AIRPLANES, OR OPERATE DANGEROUS EQUIPMENT BECAUSE THEY CANNOT STAY AWAKE?

Public policy concerning somnolence on the roads, in the airways, and in the work place is virtually nonexistent.

Generally speaking, the obstacle for sleep reseach has been "lack of designated responsibility" within HHS. Research in sleep disorders cuts across the fields of pulmonary medicine, neurology, psychology, gerontology, and psychiatry. It does not fit neatly into the missions of any one HHS institution. In 1984, the amount of Federal research money devoted to sleep research amounted to one half of one percent of the amount the public spent on health care for sleep pathologies. This is a very low ratio compared with other disease categories. In this fiscal year, the proposed reduction from 6,500 to 5,000 new and competing grants represents a reduction of 23%. We applaud your committee's efforts to reverse the OMB directive. But this proposed cut has already reduced funding for sleep research by over 90%. Laboratories have been closed even though the reduction is not yet a fait accompli.

In this era of molecular research, the neurochemistry and molecular biology of sleep, which accounts for a third of our existence and a major share of all our pathology, and above all, is required to enjoy God's gift of alertness and consciousness, we must be able to address the key research questions.

Here are our recommendations: the laudable TRANS NIH Committee should include true sleep scientists. This would have the effect of reducing the bias of the mission-oriented institutes.

The government must foster at least a few centers of excellence in sleep research around the country. It should also encourage private foundations to do the same. Sleep research is the quintessential multidisciplinary basic research commitment. It is the failure to recognize this that has created a crisis in basic research on the sleeping brain.

This advisory committee should be extended to all agencies. Creative industry/government/university partnerships should be fostered.

Thank you for the opportunity to present our views.

Senator ANDREWS. In the years that I have been on the Appropriations Committee—and I think it is more than 20 now—most of it over in the other body—I have found that we have the unlimited ability to ask questions.

But also the great challenge is that we do not know which questions to ask. If you were sitting on the other side of the table, on our side of the table, what questions would you ask NIH, in your field?

Dr. DEMENT. I would say how many people in the United States—how many scientists have grants to work on the fundamental issues? What is the sleeping brain doing? What are the cells in the brain doing during sleep? How is it working? What chemicals is it synthesizing?

I think they would have to answer there are 10,000 neuroscientists in the United States studying the waking brain and fewer than 10 studying the sleeping brain. And when you think the sleeping brain—one-third of our lives is sleep. And the sleeping brain is active in doing work to keep us alive, in doing work so we can be alert all day long. That is a disproportion of staggering——

Senator ANDREWS. Do you think there are significant differences between the sleeping brain and the waking brain?

Dr. DEMENT. Very significant. That is an excellent question.

Senator ANDREWS. And by studying the brain while individuals are awake, you cannot understand the brain during sleep stage?

Dr. DEMENT. That is right. That is right. Absolutely true. You have put your finger right square on the mark.

We need young neuroscientists coming up to study the sleeping brain with the modern technology that is currently available. The technology is available, but there are no young scientists coming along because the mandate is not there, the expertise is not there, the interest and the policymaking. So just add a few expert voices and I think that is——

Senator ANDREWS. Thank you very much, doctor, for a very challenging statement and some interesting responses to my questions. We appreciate your coming.

Dr. DEMENT. I thank you for your excellent question and thank you for your time.

STATEMENT OF NORTON NELSON, PH.D., ASSOCIATION OF UNIVERSITY ENVIRONMENTAL HEALTH SCIENCES CENTERS, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Senator ANDREWS. Our next witness is Dr. Norton Nelson, with the Association of University Environmental Health Sciences Centers. It is good to have you here.

Mr. NELSON. Thank you, Senator.

I am glad to be here. I start with an apology for my successor, Arthur Upton, who is the director of our institute and president of the association, who was unable to be here today. He was kind enough to ask me to fill in for him.

Senator ANDREWS. He sent a very able, shall we say, substitute.

Mr. NELSON. Thank you.

I would like to add that a long career has been spent totally in this field and I would like to believe that it has been effective in helping to build a solid core of this highly specialized group. I will tell you, in just a minute or two, more about that.

May I paraphrase this?

Senator ANDREWS. I will assure you, as I assured your prior witness, that your entire statement will be in the record, as though you uttered every word of it and you can leave the balance of your 5 minutes for disposition however you choose.

Mr. NELSON. It was submitted in the appropriate time and is part of the record and I thank you for that, sir.

The Association of Environmental Health Centers grows out of a program which goes back very early in the national concern for health disorders arising out of chemical and physical factors. Our bag is to look into what technology does that is nasty to people and to find ways of identifying those and find ways of avoiding further health impact from those.

We consist of a total of 15 centers and universities throughout the country. Ten of these are primarily, or should be, exclusively health-related, if that is an appropriate term. Five of these are marine and freshwater centers which deal with the health impact on water quality.

They represent a small group which fulfills, I think, a very important national role in that they house career scientists who are ready at the drop of a hat, so to speak, to enter into issues relating to such health impacts. And without prior training, necessarily. Without prior brooding over the issue.

That is not to say that all of the health related research in environmental factors come from these centers, they do not. But we are a focus. And, in fact, we can call on our sister faculties in the other centers in order to spread the good word and to take care of these issues.

As such, we are interested primarily in research and training, training at medical schools, schools of public health, training for a small number but a critical number of future specialists in this field. And we thus keep alive that flame within such centers concerned with these issues. It does provide, then, for a small cadre of person who are ready to go to work to convert the best of basic science into interest in and skills in—I may say that Friday night I was with Dr. Upton, I should mention it. My successor, Dr. Upton, was formerly Director of the National Cancer Institute, a very distinguished scientist.

He picked up the phone and the health commissioner of New York State was on the line, saying would you be able to marshal your resources to get to Kennedy Airport to see if we could monitor some of the returnees from Russia. And of course, we can. We are one of the few centers who are fully equipped, in addition to Brookhaven and some other national laboratories, for this kind of thing.

In fact, in his testimony, he identifies a total of 12 issues which have been brought to us, ranging from Love Canal to the Binghamton office fire. So we are not only concerned with basic research, we are a resource which can march into national and, in fact, in some cases international issues to aid these problems.

Now, the Bhopal episode, a national team was sent down and one of the members of that team was one of the directors of the NIHS centers.

I have appeared before this committee for a good number of years. You will forgive me if I read a few words from 1960 testimony for Mr. Fogarty. This is one of the few things I will read. I said, at that time, in 1960:

> The major source of our present interest in environmental health is the very machinery of our present day civilization itself. It is appropriate, I believe, to focus primary attention on the fact that technical advances bring with them health threats and, equally, the obligation to develop the competence to ensure that cost does not outweigh the gain. And in fact, this cost not outweighing the gain is an important ingredient in all of our concerns.

PREPARED STATEMENT

Our efforts, we like to believe, are appropriate to the need, but not excessive. Let me simply say, without further enlargement, that we believe that this modest resource is important to the Nation. We are leading the world and we would like to see that and, despite the exigencies and pains of Gramm-Rudman, we would hope that means will be found to sustain the effort without loss of impetus or loss of excellence.

[The statement follows:]

STATEMENT OF NORTON NELSON

My name is Norton Nelson. I am Professor of Environmental Medicine in the Institute of Environmental Medicine, New York University Medical Center. I was Chairman of the Department and Director of the Institute of Environmental Medicine for some 26 years, a position which I relinquished some five years ago. I have been succeeded by Dr. Arthur Upton, former Director of the National Cancer Institute, who unfortunately is unable to appear today. I remain full time in teaching and research in the Institute.

This statement is on behalf of the Association of University Environmental Health Centers. This Association represents fifteen university-based research Centers throughout the United States of which ten are health oriented and five focus on the relationship between health and the quality of fresh and marine water. These Centers constitute nucleii of stable assemblies of scientists with career commitments to the health effects of environmental agents. As such, they represent a small but highly skilled cadre of scientists who are wholly committed to research and teaching in this field.

The University-based Centers are at Duke University, Harvard University, Johns Hopkins University, Massachusetts Institute of Technology, Mt. Desert Island Biological Laboratory, Mt. Sinai School of Medicine, New York University Medical Center, Oregon State University, University of California at Berkeley, University of Cincinnati, University of Rochester Medical Center, University of Washington, University of Wisconsin at Milwaukee and Vanderbilt University.

Although obviously, these Centers do not conduct all the ongoing research important in and relevant to environmental health problems, they nevertheless have an influence which goes far beyond their numbers. This influence takes a number of forms: the ability to enlist cooperation from their sister departments in the universities outstanding investigators who then collaborate in a variety of research efforts with each other and the Centers in bringing additional skills to bear on these problems. The input of the Centers is also felt through the extent to which their scientists are called upon to provide guidance and advice in these matters to all the national agencies, to the local, state and regional bodies, and to the public.

In addition to the research in these Centers, teaching at a variety of levels is going forward to provide for continuity in the maintenance of these national resources. The professionals who are trained find positions in industry and government as well as in universities.

A guiding principle in the mission of these Centers is the endeavor to bring the very best of basic science currently available to improvements in the control of environmental health problems. These Centers have much diversity in terms of their specific scientific objectives and the skills of their faculties.

Another point relates to the need for institutions which can respond to acute emergency events. The National Institute of Environmental Health Sciences conducts such investigations in its laboratories in North Carolina as well as through its Centers, grantees, and contractors. When the catastrophic release of methyl isocyanate occurred in India in December 1984, NIEHS immediately dispatched a senior scientist to the scene. Another member of the team was Director of one of the NIEHS Centers. In just a few weeks after the incident, specific experiments using animal models were designed in North Carolina to answer fundamental questions about the probable longer-term health effects among the thousands of survivors. The results of these studies are already in the public domain. They indicate that serious lung conditions can be expected to remain, but that other toxic effects are much less likely to be seen. Such resources are critical additions to the Nation's scientific defense against environmental emergencies and must be retained.

In March 1960, I appeared as a witness before the House Committee chaired by Mr. Fogarty to report on environmental health problems. As those proceedings stated: ''...the major source of our present interest in environmental health is the very machinery of our present-day civilization itself... It is appropriate, I believe, to focus primary attention on the fact that technical advances bring with them health threats and, equally, the obligation to develop the competence to insure that the cost does not outweigh the gain.''

That simple point is still true today, after some 26 years of expansion of the technologic base of our modern society, and after 26 years of advancement in the state of knowledge in the relevant scientific disciplines related to safety, we have been successful in developing techniques to measure the potential health risks of many hazardous compounds found in the air, soil, water and foods. But we still have a long way to go. Using these methods, we have clearly described some of the health risks of such ubiquitous substances as benzene. We have shown that asbestos can pose significant threats when inhaled, but when present in water which is ingested is of far lesser and perhaps negligible risk. It is as important to know which substances are not hazardous as it is to know which do indeed cause disease; this balance of findings is of critical importance.

There are still untested tens of thousands of substances being manufactured of which many are present in the environment. Test procedures at this time are expensive, time-consuming and often not adequately sensitive. They need improvement. Procedures in minimizing the amount and toxicity of hazardous wastes and in cleaning up disposal sites have had virtually no input of modern sciences.

I am, thus, particularly concerned about the future of environmental health sciences research today. In 1960, we were just beginning to realize the importance of the impact the environment could have on chronic disease morbidity and mortality in the United States. In the interim, the Environmental Protection Agency was established, and key pieces of environmental legislation have been enacted to protect the quality of our air and water. Pesticides and other chemicals used to control rodents, weeds, and fungi are tested. Strong laws now govern the environment and its effects on health.

Accordingly, the most basic question you must ask is, why continue to sustain this level of effort in the face of competing demands for scarce Federal resources and after tough environmental protection legislation and regulation is in place? In my opinion, we need the focus for environmental health research now, just as we needed it in 1960. The underlying science is improving but not yet fully adequate to meet the expectations stimulated by this legislation.

- Environmental health sciences research is cost-effective. Basic toxicologic research yields information that can either implicate or exonerate a compound as a potential cause of illness or adverse reproductive outcome, and we have begun to build a solid foundation for responsible, defensible risk management and regulatory actions.
- The discipline of modern environmental health sciences is only now entering a period of its most productive maturity. We are now emerging into a scientifically sophisticated period in our assessment of health risks.
  We must know more about how hazardous substances affects our cells, our metabolic processes, and vital organ systems. As we begin to unravel these questions, we will get clues as to how to interrupt the process and perhaps prevent the outcome of exposure.
- There are unanswered questions about the impact of multiple exposures and exposures to combinations of toxicants which have not yet been addressed. Very little is known about the health effects of exposures to complex mixtures.

To turn now to some specifics on the Centers. One of the Centers has developed a personal testing device which measures individual exposure to external and indoor air pollutants with convenience, accuracy, and at low cost. The principles used in this have now been widely applied in occupational and environmental studies of air pollutants.

The device and the principle have been picked up by private industry and is available from several manufacturers.

As noted earlier, one of the major objectives in the Centers is to carry out the research and development necessary to enable the best basic science currently available to be applied to public health problems. An example of this is the exploitation in Centers of advances in our understanding of oncogenes. These are genes which in the organism have the potential of becoming activated (bv chemical carcinogens among other ways) and thus capable of giving rise to cancer; such research can significantly improve methods for the study of carcinogens.

Several Centers are now developing new techniques called molecular epidemiology. These are based on recent findings that the reaction of chemical carcinogens with DNA in exposed persons can be detected in easily accessible blood cells. These techniques may provide means for the early and more certain detection of exposure.

In addition, there are many research inquiries underway in the Centers, a very selective listing includes:

- patterns of mutations in accessible human blood cells may indicate the nature of toxic exposures
- identification of genes involved in repair of DNA damaged by ultra-violet light is underway
- analysis of DNA bases in urine from injured DNA as measure of mutagen exposure
- study of mutagens in natural products
- the role of protease inhibitors in suppressing cancer is being examined
- epidemiological studies of a wide variety are underway: air pollution, ambient and indoor, neurologic and renal disorders, breast cancer, exposure to heavy metals, ionizing radiation, occupational factors, hair dyes; all of these will involve estimates or actual measurement of exposure levels

- studies of mercury in disease including estimates of health impact of mercury dental fillings
- role of low-level lead exposure in utero on impairment of growth and mental development
- mechanisms of neurotoxicity, including techniques to measure the effects of potential neurotoxic agents on dopamine, acetylecholine, and serotonin receptors in brain
- behavioral effects of chemicals
- studies of molecular genetics in aquatic systems as an aid to understanding human systems
- development of aquatic test systems as replacement for mammalian systems
- and many other research programs

I realize that in coming before you to plead the case for the continuing support of the NIEHS Centers, I do so amidst anguishing times. The dilemma of the Gramm-Rudman-Hollings law is making it necessary for Congress to make very difficult decisions affecting Universities. I can only say that we, in the Universities, are fully aware of the dilemma arising from the major national deficit we are now facing and that return to more stable financing will require sacrifice on many fronts. I plead that this is no time for the Centers to be cutback in their funding; they are at best, only staying abreast of needs because of earlier limited funding. We thus, hope that cutbacks will not be imposed but that you will find it possible to maintain these resources by continuing funding of these Centers at the current level plus inflation rate and with a modest increment. If this can be done, we believe that it will be possible to conserve the impetus now developed and to maintain a sufficient level of activity to permit the continued and appropriate development of these Centers. Similarly, NIEHS itself must, at a minimum, maintain its in-house program as well as its training and individual research support; these should include inflationary monies and a modest increment.

Senator ANDREWS. Thank you very much for an excellent statement and I appreciate your pinch-hitting for your successor. It is not very often that we get someone who has been testifying back over the years.

Mr. NELSON. It goes back to 1954, Senator.

Senator ANDREWS. Well, John Fogarty and I served together on the House Appropriations Committee and he introduced me to a delightful lady by the name of Mary Lasker.

Mr. NELSON. I know her well.

Senator ANDREWS. You undoubtedly know her and——

Mr. NELSON. In fact, I may have testified before you in an earlier—she is a very valuable lady and she has been very friendly to this program and, indeed, to our points.

If I may just take one more word, Mr. Fogarty—in one of the sessions on the other side of the House—said Dr. Nelson, you are in a very small specialty. Do you sometimes worry about your future. I said I always worry about the future of the program. He said, at that time, is there some means that we should explore to maintain a small spark of life in this program over the dark days that may be coming?

And that was really the impetus which lead to the formation of those NIHS centers.

Senator ANDREWS. Thank you for an excellent statement, doctor.

Mr. NELSON. He was a valuable person and, in fact, he gave the dedicatory speech for our own institute.

Senator ANDREWS. He did, that is right.

STATEMENT OF ALAN C. DAVIS, CHAIRMAN, COALITION STEERING COMMITTEE, COALITION ON SMOKING OR HEALTH

ACCOMPANIED BY BECKY LANGAGER, LEGISLATIVE REPRESENTATIVE, AMERICAN HEART ASSOCIATION

Senator ANDREWS. Our next witness is Mr. Alan Davis, the chairman, Steering Committee on Coalition on Smoking OR Health.

Mr. Davis, good to have you here.

Mr. DAVIS. Senator, it is an honor to be before you, today. As you said, I am Alan Davis and I am vice president for government relations and the science editor of the American Cancer Society. I appear before you today as the chairman of the Steering Committee of the Coalition on Smoking OR Health.

The Coalition on Smoking OR Health was formed by the American Heart Association, the American Lung Association, and the American Cancer Society in January 1982 to bring the health hazards of cigarette smoking more effectively to the attention of legislators and other public officials.

My lovely associate, Becky Langager is legislative representative of the American Heart Association here in Washington.

We are pleased to appear before your subcommittee today to make our funding recommendations for the Federal Office on Smoking and Health [OSH]. We say "OR Health" and the Government says "and Health."

The Office of Smoking and Health is the Federal focal point for all Department of Health and Human Service [HHS] tobacco and health activities and serves as a national and international clearinghouse for scientific, technical, and general public information regarding cigarette smoking and the use of smokeless tobacco. The functions of the OSH are diverse but generally fall into three categories: collection and dissemination of scientific and technical information; public education; and regulatory activities. Each of these areas is described, in detail, in my written statement.

Cigarette smoking is the No. 1 preventable cause of death and disability in the United States. Over $22 billion annually in health care costs and $43 billion annually in loss of productivity costs, including over $4 billion annually in Medicare and Medicaid costs can be attributed to smoking. This $65 billion yearly is in addition to the incalculable human toll of pain and suffering which results from the 1,000 deaths per day because of smoking-related causes.

Use of smokeless tobacco products—snuff and chewing tobacco—is also a serious health problem. The National Cancer Institute estimates that 6 to 12 million Americans use these products. What is most disturbing about this consumption figure is the increase it represents in the number of male teenagers using smokeless tobacco. The use of smokeless tobacco will lead to a significant increase in oral cancer deaths in this country.

The public health problems that are encompassed by the OSH mandate are enormous. The office does not attempt to tackle these problems alone; we in the voluntary sector take a very active role in educating the public regarding the health hazards of cigarette smoking and the use of smokeless tobacco. However, we believe that OSH's role as the central coordinator for the entire national and international health community for tobacco education and data collection efforts is crucial.

The OSH accomplishes all of its tasks with minimal resources, a current budget of only $3.24 million, and 17 staff positions. No funding has been added to the OSH budget while Congress has given it increased public education and regulatory responsibilities. When one takes into account the staggering fact that the tobacco industry spends approximately $2 billion annually on advertising its products, it becomes obvious that even the combined resources of the OSH and the voluntary health organizations that I represent are not sufficient to counteract the sophisticated advertising techniques employed by the industry to entice individuals to begin or continue smoking.

The President's budget includes $3.47 million for the OSH in fiscal year 1987. We do not believe that this level of funding is sufficient for the office to carry out all of its current and newly mandated functions. Therefore, we recommend that the office receive a fiscal year 1987 appropriation of $4.738 million and that they receive a full-time equivalent [FTE] increase of eight positions.

The Coalition on Smoking OR Health and its member organizations believe that without the many functions performed by the OSH, the effort to educate the American public and the rest of the world about the health hazards associated with smoking would be far behind where it is today.

I am here today, Mr. Chairman, on behalf of the Coalition on Smoking OR Health, to urge the subcommittee to approve adequate funding for this small, but most effective, Federal office. Hundreds of thousands of lives are depending on it.

Thank you.

PREPARED STATEMENT

Senator ANDREWS. Thank you very much, Mr. Davis, for an excellent statement.

[The statement follows:]

STATEMENT OF ALAN C. DAVIS

My name is Alan Davis and I am Vice President for Government Relations and Science Editor for the American Cancer Society. I appear before you today as the Chairman of the Steering Committee of the Coalition on Smoking OR Health. The Coalition on Smoking OR Health was formed by the American Heart Association (AHA), the American Lung Association (ALA) and the American Cancer Society (ACS) in January of 1982 to bring the health hazards of cigarette smoking more effectively to the attention of legislators and other public officials. These three voluntary health organizations are among the oldest and largest organizations of citizen volunteers in our country; together they have a membership of almost five million volunteers. We are pleased to appear before your Subcommittee today to make our funding recommendations for the Federal Office on Smoking and Health (OSH).

The Office on Smoking and Health is the Federal focal point for all Department of Health and Human Services (DHHS) tobacco and health activities and serves as a national and international clearinghouse for scientific, technical and general public information regarding cigarette smoking and the use of smokeless tobacco. It is located within the Office of the Assistant Secretary for Health. The functions of the OSH are diverse but generally fall into three categories: collection and dissemination of scientific and technical information; public education; and regulatory activities. Each of these areas is described in detail below.

Cigarette smoking is the number one preventable cause of death and disability in the United States. Smoking causes 80 percent of all lung cancer deaths and is a significant cause of cancer of the larnyx, oral cavity, esophagus, bladder and is significantly associated with cancer of the pancreas and kidney. Cigarette smoking is a major risk factor in the development of cardiovascular disease and causes one-third of all heart disease deaths. Smoking is a major cause of emphysema and chronic bronchitis and causes 80 - 90 percent of all deaths due to these diseases in the U.S. Over $22 billion annually in health care costs; $43 billion annually in lost productivity costs; and over $4 billion annually in Medicare and Medicaid dollars costs can be attributed to smoking. This $69 billion yearly is in addition to the incalculable human toll of pain and suffering which result from the 1,000 deaths per day because of smoking-related causes.

Use of smokeless tobacco products -- snuff and chewing tobacco -- is also a serious health problem. The National Cancer Institute estimates that 6 to 12 million Americans use these products. What is most disturbing about this consumption figure is the increase it represents in the number of male teenagers using smokeless tobacco. The use of smokeless tobacco will lead to a significant increase in oral cancer deaths in this country. In addition to causing oral cancer, smokeless tobacco produces the following additional adverse health effects: decreased taste and smell sensations; staining of and abrasion of tooth surfaces; advanced periodontal destruction and possible tooth loss; soft tissue losses; and significant increases in heart rate and blood pressure.

The public health problems that are encompassed by the OSH mandate are enormous. The Office does not attempt to tackle these problems alone; we in the voluntary health sector take a very active role in educating the public regarding the health hazards of cigarette smoking and the use of smokeless tobacco. However, we believe that OSH's role as the central coordinator for the entire national and international health community for tobacco education and data collection efforts is crucial. I would like to provide the Subcommittee with a detailed description of the many activities of the OSH.

Science and Technical Information

The OSH Technical Information Center (TIC) is a vast repository of current research in smoking and health. The TIC regularly disseminates information to over 5,000 researchers and health professionals. The TIC is the world's only international clearinghouse for scientific information on smoking and health.

The major publication of the OSH is the Annual Surgeon General's Report on The Health Consequences of Smoking. This document is recognized throughout the world as the premier publication on current issues in smoking and health research. The next issue of the Surgeon General's report, due out in November, 1986, will focus on the issue of involuntary smoking and its impact on the health of nonsmokers. The topic for the 1987 Surgeon General's Report is the benefits of quitting smoking. Other TIC publications include:

- Directory of On-Going Research on Smoking and Health -- the current issue contains over 1,500 research projects from the United States and 40 other countries.
- Bibliography on Smoking and Health -- lists abstracts of 2,000 new studies published annually.
- State Legislation on Smoking and Health -- annual listing of all state laws enacted dealing with taxation, restrictions on smoking in public places, smoking health education in schools, commerce and other areas.
- State and Local Programs in Smoking and Health -- a listing of over 800 programs at the state and local level that serve as a resource guide and referral mechanism for physicians and other health professionals.

The TIC is also responsible for conducting periodic surveys on the smoking habits and characteristics of various segments of the U.S. population; analyzing existing smoking and health data sources; and providing technical assistance to researchers and other health professionals involved in special analysis of smoking and health issues. For the first time, OSH is now able to generate national and statewide smoking prevalence data obtained in cooperation with the the Census Bureau's Current Population Survey. This activity represents the largest survey on smoking ever conducted. A report on this data will be published by the OSH this summer. Another survey on which the Office will be reporting is on public attitudes and beliefs about smoking. This report should be completed by the end of 1986.

The TIC continues to serve as the world's only international clearinghouse for scientific information on smoking and health and is a World Health Organization Collaborating Center for Smoking and Health. By August of this year, the Office is expected to have its entire on-line search and retrieval system available for use by outside organizations and individuals at no cost to the Federal government. Over 40,000 scientific titles will be available via computer access for a small user charge.

Public Information and Education

The public information activities of the OSH have been very successful. Television networks and stations have given OSH Public Service Announcements (PSA's) on the health consequences of smoking more free air time than those produced by any other Federal or nonfederal agency. A recent evaluation found that OSH PSA's aired an average of 25.8 times per month and over 64 percent of these spots were aired during peak viewing times. The value of this air time is in excess of $10 million. Recent examples of the Office's public information and education activities include:

- Secretarial Initiative on Smoking and Pregnancy -- a combination of TV and radio announcements, a news video, posters (in English and Spanish), pamphlets and other materials were used to convey the dangers of smoking by pregnant women.
- A Physician Talks About Smoking -- this talk was prepared by the Office for use by any physician or health care professional who is called upon to speak to medical and lay audiences on smoking and health.
- High School Ads -- a series of public service advertisements was created for high school newspapers. This is the first time this medium has been used by a Federal health program.
- The Smoking Monkey Campaign -- this public service announcement on the health hazards of smoking was jointly sponsored with the American Cancer Society and proved to be a great success.

One specific comment I would like to make about the public information and education activities of the OSH is that because they do their job so well, their own products are not always highly visible. They often produce public information materials -- PSAs, pamphlets, brochures, draft papers and speeches -- that are used by other organizations, with the credit for that material going to that organization or group. This especially benefits smaller, local community and health organizations that do not have the resources to produce such materials.

In addition to its information and education programs on the health effects of cigarette smoking, as a result of the enactment of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (P.L. 99-252), the Office has been designated as the lead agency for the development of educational programs and materials about the health hazards of the use of smokeless tobacco products.

Regulatory and Reporting Activities

The regulatory and reporting activities of the OSH are its newest areas of responsibility. The enactment of the Comprehensive Smoking Education Act (P.L. 98-474) in 1984 not only statutorily established the OSH, but required the Office to perform several new reporting and regulatory functions. The legislation requires the Office to staff the Interagency Committee on Smoking and Health, including the preparation of a biennial report to Congress on the activities of the Office, as well as the private sector, and about the efforts undertaken by each to inform the public of the health hazards of smoking.

The Office is also charged with the important task of compiling and reporting on cigarette ingredients information to be supplied to the DHHS by cigarette manufacturers as mandated by P.L. 98-474. This ingredients report to Congress must include information regarding any ongoing or proposed research activities on the health effects of tobacco additives and any other information on ingredients which pose a health risk to smokers. This information must be transmitted to Congress on a regular basis and must be made available to individual members of Congress or Congressional Committees upon request.

The comprehensive smokeless education act contains similar provisions for collecting and reporting on additives in smokeless tobacco products. In addition, the law requires a report to Congress describing the effectiveness of health education efforts about the adverse health effects of smokeless tobacco use; smokeless tobacco consumption figures; a description of the health effects of smokeless tobacco use; and identification of health and consumption-related topics appropriate for further research.

So how effective has the Office been in getting its messages across to the public? While direct measurement of this is impossible, the following statistics show that a substantial impact has been made since the Federal government first began its smoking education activities. Total cigarette consumption declined by over 30 billion between just 1982 and 1984. Per capita consumption is now at its lowest level since the 1940's. Except for young females, smoking among all major age, race and sex groups has declined. In just 20 years, smoking prevalence among adult males has decreased by 40 percent. Obviously OSH cannot take full credit for these changes in smoking behavior, however, they have provided strong leadership in this area to which we, in the private sector, have responded enthusiastically.

The OSH accomplishes all of its tasks with minimal resources: a current budget of only $3.24 million and 17 staff positions. In addition, no funding has been added to the OSH budget as Congress has given it increased public education and regulatory responsibilities. In fact, OSH lost three staff positions to PHS management functions in 1985 and the Office suffered a $300,000 budget reduction due to the implementation of the Gramm-Rudman cuts and reductions in funds for consulting services this year. When one takes into account the staggering fact that the tobacco industry spends approximately $2 billion annually on advertising its products it becomes obvious that even the combined resources of the OSH and the voluntary health organizations I represent are not sufficient to counteract the sophisticated advertising techniques employed by the industry to entice individuals to begin or continue smoking.

The President's budget includes $3.47 million for the OSH in FY 1987. We do not believe that this level of funding is sufficient for the Office to carry out all of its current and newly-mandated functions. Therefore, we recommend that the Office receive an FY 1987 appropriation of $4.738 million and that they receive an FTE increase of 8 positions.

The Coalition on Smoking OR Health and its member organizations believe that without the many functions performed by the OSH, the effort to educate the American public and the rest of the world about the health hazards associated with smoking would be far behind where it is today. The Annual Surgeon General's reports are looked upon internationally as the scientific references on smoking and health related topics. OSH's collection and dissemination of the immense data base of smoking and health research, both completed and ongoing, is an invaluable resource to scientists, health professionals and public health advocacy organizations like ours. Finally, the public health activities and programs developed and implemented by OSH have added immeasurably to the gains that have been made in reducing the single most preventable cause of death in the U.S.: cigarette smoking. I am here today, on behalf of the the Coalition on Smoking OR Health, to urge the Subcommittee to provide adequate funding for this small but most effective Federal office. Hundreds of thousands of lives are depending upon it.

STATEMENT OF THOMAS McANDREW, ATTORNEY, JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

Senator ANDREWS. Our next witness is Mr. Thomas McAndrew, an attorney for the Fogarty International Center. And I will be turning the chairing position over to my colleague, the senior Senator from North Dakota.

It is good to have you hear, Mr. McAndrew.

Mr. MCANDREW. Thank you, Senator.

Senator, before you go, I heard you mention you worked in the House of Representatives with my late father-in-law, John Fogarty.

Senator ANDREWS. John was your father-in-law? John was a delightful individual. We traveled on a number of occasions to other countries when I served on the House Appropriations Committee.

Mr. MCANDREW. I recall how he and Mel Laird worked in a very bipartisan way to enhance the health sciences and to build the National Institutes of Health to the great institution that they are today.

Senator ANDREWS. Your wife can be extremely proud of having an outstanding father.

Mr. MCANDREW. He was a wonderful man.

Senator ANDREWS. It is good to have you here.

Mr. MCANDREW. Thank you very much.

Senator BURDICK [presiding]. Just in case you want to make the record complete——

Senator ANDREWS. I mean, you served with John, too.

Senator BURDICK. Just to make the record complete.

Mr. MCANDREW. Good morning. My name is Tom McAndrew and I am here from Providence, RI. I am here as a public witness to appear before this distinguished body on behalf of the John E. Fogarty International Center for Advanced Study in the Health Sciences at the National Institutes of Health. That institution came into being after my father-in-law, the late Congressman John Fogarty, died on the first day of the 90th Congress in the Longworth House Office Building of a heart attack, on January 10, 1967.

He served in the Congress for 27 years, 16 of which he served as chairman of the Appropriations, Labor, Health, Education, and Welfare Committee. In that position, he had an opportunity to consider and pass upon many of the most important pieces of health care legislation which are law today. To his lasting credit and that of the other Members of this distinguished body who have served and continue to serve, our country has become a model and standard by which all other health care institutions and practices are compared.

When Melvin Laird introduced the bill into the Congress to establish the John E. Fogarty International Center for Advanced Study in the Health Sciences, he did so out of the common belief that he and John shared that we live in an era when the attention of the world is focused on the efforts of nations to find ways to work together in common purposes.

In order to attain the highest level of health worldwide, international medical research must be promoted in the interest of scientific advances. We must support medical research performed by foreign scientists whenever such studies will advance both the health status of the United States and the country in which the research is conducted. We must avail ourselves of the unequalled and often superior opportunities for our own research agendas. By uniting different approaches, greater progress can be made in a shorter amount of time. All mankind can benefit.

While recognizing that we are moving into an era of constrained resources, careful attention to priorities and the effective use of resources is paramount. We must assure that we do not retreat from our international prospective, involvement, and leadership. It is as important as ever, if not more so, that the United States and foreign scientists continue to have opportunities to meet, discuss, and analyze their respective work; that United States and foreign scientists continue to have opportunities to collaborate in laboratories and share their unique talents toward common research objectives.

United States and foreign scientists must continue to examine together those health research issues that evolve and emerge as common worldwide concerns. Certainly, disease knows no social, economical, or political barrier.

As the focus for the National Institutes of Health's international activities, the Fogarty International Center is unique in its responsibility to further international biomedical collaboration. It does this at every level between scientists, institutions, and governments. Through its various programs that broaden international cooperation and agreement, the Fogarty International Center focuses to maintain U.S. leadership in biomedical research, while taking advantage of opportunities offered throughout the world that will enhance the health of the American people.

John Fogarty believed, Mr. Chairman, in the representative democracy. He believed in the importance of the Congress, and he believed that one person could make a difference. I am confident, Mr. Chairman, and Members of this body, that you, too, believe in many of the same ideals espoused by Mr. Fogarty and are committed in the same manner to eradicate disease and health care problems that inflict oh, so many.

In this regard, I would ask your consideration to enhance the budget request submitted by the Fogarty International Center, and particularly with the scholars and residents program as well as the international research fellowships that are provided through the Center.

Again, as I said, while recognizing that economic constraints are superimposed upon the Congress, in its having to make decisions with respect to funding of programs and activities you will weigh the relative merit of increasing activity in biomedical research, scholars, and residents, international research fellowships or any of the other worthwhile programs of the Fogarty International Center, and I firmly believe that they will somehow outweigh funding of other programs and activities that are reported to be wasteful and of no benefit to mankind.

In closing, Mr. Chairman, I'd like to thank you for having had the opportunity to come before you. There's one other thing. I've heard this $6.7 billion figure going around with respect to the NIH appropriation this morning. And I recall, if I'm not mistaken, that when John took over as chairman of that committee in the late forties, I think it was getting like $1.3 million. And through cooperation with Senator Lister Hill who worked here in this distinguished body and other Members like yourself, the National Institutes of Health has become the classiest health care organization in the world.

Thank you, Senator.

PREPARED STATEMENT

Senator **Burdick**. Thank you for your contribution this morning.

[The statement follows:]

Statement of Thomas McAndrew

Good afternoon! My name is Thomas McAndrew and I am from Providence, Rhode Island. I am here to appear before this august body on behalf of the John E. Fogarty International Center for Advanced Study in the Health Sciences at the National Institutes of Health. That institution came into being after my father-in-law, the late Congressman John E. Fogarty, died on the first day of the 90th Congress on January 10, 1967.

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When Melvin Laird introduced the Bill into the Congress to establish the John E. Fogarty International Center for Advanced Study in the Health Sciences, he did so out of the common belief that he and John shared that we live in an era when the attention of the world is focused on the efforts of nations to find ways to work together in common purposes.[1]

In order to attain the highest level of health worldwide, international medical research must be promoted in the interests of scientific advances. We must support medical research performed by foreign scientists whenever such studies will advance both the health status of the United States and the country in which the research is conducted. We must avail ourselves of the unequalled and often superior opportunities for our own research agendas. By uniting different approaches, greater progress can be made in a shorter amount of time. All mankind can benefit.

Recognizing that we are moving into an era of constrained resources, careful attention to priorities and the effective use of resources is paramount. We must assure that we do not retreat from our international prospective, involvement and leadership. It is as important as ever, if not more so, that the United States and foreign scientists continue to have opportunities to meet, discuss and analyze their respective work; that U.S. and foreign scientists continue to have opportunities to collaborate in laboratories and share their unique talents toward common research objectives. U.S. and foreign scientists must continue to examine together those major health research issues that evolve and emerge as common worldwide concerns. Certainly disease knows no social, economic or political barrier.

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[1] Congressman John E. Fogarty addressed a World Health Assembly in 1962.

As the focus for the National Institutes of Health's international activities, the Fogarty International Center is unique in its responsibility to further international bio-medical collaboration. It does this at every level between scientists, institutions and governments. Through its various programs that broaden international cooperation and agreement, the Fogarty International Center focuses to maintain U.S. leadership in bio-medical research while taking advantage of opportunities offered throughout the world that will enhance the health of the American people.

Under its advanced studies programs, the Fogarty International Center is continuing its activities dealing with those infectious diseases considered candidates for foreseeable eradication. For example, there are in the world an estimated one million persons infected with yaws, a disease previously thought to be virtually conquered. In certain regions, particularly the west and Central Africa, the situation is precarious. The proportion of children with yaws is approaching that of pre-penicillin years. In 1985 as a follow up to its 1984 international symposium on yaws, the Fogarty International Center initiated a meeting in cooperation with the World Health Organization, held in Indonesia, of Asian countries to stimulate and strengthen primary health care services by coupling curative treatment with prevention (immunization).

As I understand it, future activities include a 1986 meeting on yaws to determine the present epidemiological situation in the African region and to consider integrated control measures in the cost of implementing yaws treatment in children as part of the primary health care services in each country. The Fogarty International Center, together with a number of international organizations, is working to transfer state of the art research results in the form of newly developed diagnostic techniques. The Institute is also taking advantage of research opportunities in this initiative to study penicillin resistance to the agent causing yaws. Such research is important because of penicillin resistance in the closely related organisms that cause syphilis. It is further important to obtain this information to avert a potentially greater problem worldwide.

The Fogarty International Center International Research and Awards programs sponsored foreign scientists to work in U.S. laboratories and sent U.S. researchers to foreign scientific institutions to conduct research of mutual interest covering a wide range of scientific approaches. Their research is concentrated in areas of every current global health concern, most generally metabolic and infectious diseases. Such programs not only contribute to the development of scientists and their country's resources, but more importantly, insure the continuation of American influence and leadership in bio-medical science.

In its role as the operational link between the National Institutes of Health and other U.S. agencies and international organizations concerned with problems of world health, the Fogarty International Center facilitates the National Institutes of Health's collaborative relationships in bio-medical research with over 70 countries. Among these countries, China and India, are of priority interest to the U.S. government for maintaining strong cooperation in science and technology. With both countries, the NIH has major linkages of mutual benefit developed through the efforts of the Fogarty International Center. One of the several activities with China which the Fogarty Institute facilitated is the development of an understanding with the Chinese academy of medical sciences to implement a health scientist exchange program that is intended to foster contacts between scientists in areas outside those under the existing agreements.

In the instance of India, the Fogarty International Center is coordinating NIH requirements for funding under the new U.S.-India fund for cultural, educational and scientific cooperation. This fund will support projects being proposed by NIAID, NHLBI, DRS, NIDR and NLM and thus U.S. owned Rupees will generate interest that can be used for U.S. projects.

The Fogarty International Center plays a key role in the technical management of a new major program with India: the vaccine action program which was announced by President Reagan and Prime Minister Ghandi following the Prime Minister's state visit in June of 1985. This new program follows other successful collaborations in science and technology but differs in that it is focused on disease and can be prevented though immunization programs, rather than on a particular component of technology. It is comprehensive, covering a broad range of activities from basic research and development of new and improved vaccines to strengthen the quality control and vaccine manufacturing capability in the Indian private sector. The vaccine action program incorporates interest both in science and technology collaboration and in immunization programs, the latter a critical feature of child survival programs throughout the country. In addition, the vaccine action program will provide an opportunity for U.S. scientists who are working on vaccine development to pursue their studies through field study phase, an opportunity all too frequently unavailable.

In its role as the world health organization collaborating center for research and training in bio-medicine, the Fogarty International Center sponsored in cooperation with the Gorgas Memorial Laboratory, the Pan American Health Organization and others, a work shop on training needs in entymology for vector bone disease research and control, held in Panama in October of 1985. This project should be a significant factor in furthering regional and global strategies and manpower development for control of major vector born diseases. Further, in cooperation with the PAHO and the WHO, the Institute is currently conducting a project in the region of the Americas to identify patterns of international research collaboration between developed and developing countries. As a result of this project, it is expected that the Institute will be able to recommend strategies for strengthening health research capabilities of scientists to participate in the research mission of the National Institutes of Health. Of course, the Gorgas Memorial Institute and its laboratory in Panama receive cost support from the Fogarty International Center appropriation. The Fogarty International Center has supported site visits to the laboratory to encourage the strengthening of their research and is urging the Institute to develop additional sources of funding so that the laboratory may continue to be an important resource for the United States.

The Fogarty International Center also provides the Scholars-In-Residence program which was established in 1969. Here, outstanding scientists and scholars are invited to the National Institutes of Health to collaborate with the scientific community and to contribute to the National Institutes of Health intellectual environment through research, seminars, lectures and conferences. Scholars pursue individual studies of subjects of mutual interest to them and the NIH. Appointments are for up to 12 months which can be taken in two terms over a three year period. This program offers scholars the unique opportunity to focus on research and writing that they might not otherwise be able to undertake. As I understand it, to date, a total of 131 scientists have participated in the program. While most have come from Western Europe, North America, Japan and Australia, there are others who have participated from the Far East. In fiscal year 1985, 31 such scientists participated in the program, 10 of whom were newcomers.

The collected bibliography now includes upwards of 500 titles since 1970, including over 60 monographs, numerous reviews of major topics and bio-medical research in over 400 original articles in international referee journals. During 1985 alone, 45 papers were published by scholars who participated in the program since 1983. For example, scholars publish papers on the development of vaccines against leprosy; the development of synthetic antigenens for preparation of hepatitis vaccines; the relationship between celluar oncogene expression and hematopoietic development; and a book summarizing knowledge about the characterization in synthesis of information-bearing peptides which include many hormones and nutra-transmitters.

John Fogarty believed in a representative democracy. He believed in the importance of Congress and he believed that one person could make a difference. I am confident Mr. Chairman and members of this body that you, too, believe in many of the same ideals espoused by Mr. Fogarty and are committed in the same manner to eradicate disease and health care problems that inflict oh so many. In this regard, I would ask your consideration to not only support the request submitted by the administration on behalf of the Fogarty International Center but would ask you to consider supplementing that to enhance the Scholars-In-Residence program as well as the International Research Fellowships that are provided through the Center. While recognizing the economic constraints superimposed on the Congress and its having to make decisions with respect to funding of programs and activities sponsored, when you weigh the relative merits of increasing activity in the bio-medical research area, Scholars-In-Residence or International Research Fellowships or any of the other worthwhile programs in the Fogarty International Center I firmly believe that they will somehow outweigh funding of other programs or activities that are reported to be wasteful and of no benefit to mankind.

In closing, I would like to thank you Mr. Chairman and other members of the Committee, for having had this opportunity to come before you for it has been a distinct pleasure. Thank you!

STATEMENT OF HAMILTON B. WEBB, M.D., VICE CHAIRMAN, BOARD OF DIRECTORS, GORGAS MEMORIAL INSTITUTE ON TROPICAL AND PREVENTIVE MEDICINE, INC.

Senator BURDICK. The next witness is Hamilton Webb, M.D., vice chairman, Board of Directors, Gorgas Memorial Institute on Tropical and Preventive Medicine.

Dr. WEBB. Good morning, sir. I'm very happy to be here, sir.

The Gorgas Memorial Institute operates the Gorgas Memorial Laboratory in the Republic of Panama, and it has been supported for about 56 years by a contribution from the Congress. Mr. Lister Hill, whose name has been mentioned, was one of the initiators of the Gorgas Memorial Laboratory.

Our budget—let's say our appropriation in 1981 was $1.8 million. It has come up the last year to $1.999 million, and this year we will be about $83,000 less than that, according to predictions.

We have had to close the middle America research unit which was given to us on loan you might say by infectious diseases in NIH in 1975. It had to be closed and we eventually had to close it. It cost $500,000 in severance pay and moving charges and so forth, and we had to borrow this money from the Republic of Panama because it was unprovided otherwise. We're paying this back at the rate of $100,000 a year.

There's a lot of work to be done down there. As an example, I might point out that acquired immune deficiency syndrom [AIDS] is a tropical disease which escaped the tropics. We try to keep yellow fever from escaping the tropics by our monitoring programs down there which are very active. We keep an eye on a disease called St. Louis encephalitis which does appear in human children down there. It's very severe when it occurs in adults, but we find it in children in Panama.

And we do a great deal of work on our core funds in maintaining tissue cultures which are used by several other nations and other universities, maintaining registers of different kinds of insects, and in doing a good deal of basic work in the nature of the transmission of disease by insects to human beings.

We think there's a great deal more to be done and we'd like to do it. But we have to account for inflation by reducing our programs, and we would very much like to have increased support from the House and the Senate Appropriations Committees in order that we can do some of the work. We think there's a lot of it that needs to be done.

We would like to train more people. We train now, under a Navy contract, some Navy medical officers in tropical medicine. We would like to do a good deal more of that.

We have relationships with a number of universities, exchange programs, collaborative programs. We serve as a field station for field trials for drugs, such as malaria drugs. We have a large colony of the only monkey which harbors human malaria. It's the aotis monkey and we have been doing trials on malaria—animal malarial drugs in those animals.

This colony also gives us an opportunity to study liver disease and other parasitic diseases, and these things are all carried on with the core funds which the Congress provides.

PREPARED STATEMENT

I'd be happy to answer any questions, sir, and I would like to say I wish we could do more. I think there's a lot more to be done.

[The statement follows:]

STATEMENT OF DR. LEON JACOBS, CHAIRMAN, BOARD OF DIRECTORS, GORGAS MEMORIAL INSTITUTE OF TROPICAL AND PREVENTIVE MEDICINE, INC.

I am Leon Jacobs, Chairman of the Board of Directors of the Gorgas Memorial Institute of Tropical and Preventive Medicine, Incorporated (GMI). My curriculum vitae is attached to my written statement.

Three years ago I came before this Subcommittee to request reinstatement, in the appropriation of the Fogarty International Center of the National Institutes of Health, of the annual contribution to the Gorgas Memorial Institute which had been deleted from the administration request for fiscal year 1984. The Congress has, since 1928, provided an annual contribution to GMI for the operation of the Gorgas Memorial Laboratory (GML) in Panama. This contribution has been channeled, administratively, through the Fogarty International Center, since 1971. Prior to that year, the National Institute of Allergy and Infectious Diseases was the agency administering the contribution, and before that arrangement was made in 1958, the Department of State passed the funds to GMI.

Because GMI was classified by NIH as a "center", and because NIH was planning to delete support for some centers in its modified appropriation request in the Spring of 1983, the request for funds for GMI was removed from the altered request for the Fogarty International Center. In letters to you and to Congressman Natcher and his colleagues in the House Subcommittee, and then in statements I made before your and his committees, I pointed out that the Gorgas Memorial Institute and Laboratory would be dead unless funding was restored. You and your colleagues rescued us, on the basis of reports prepared by the Office of Technology Assessment (OTA) and the General Accounting Office (GAO). Their reports recommended continued operation of GML and suggested that improvements be made in management and that GMI seek outside funds for enhanced support.

In 1984 and 1985, I was able to report to you that the Gorgas Memorial Laboratory was consolidating its operations and its facilities in Panama City and giving up the expensive Building 265 in the former Canal Zone. Personnel reductions had been accomplished and refurbishing of laboratories to bring all the units together was proceeding. Last year I could tell you that the GML had grants and contracts for about $1,000,000 for research and training. The major items among these projects are still in operation this year. These are epidemiological studies of human T-cell leukemia virus in Panama; epidemiology of cervical cancer in Panama, Colombia, Costa Rica and Mexico, for which GML is the prime contractor; malaria drug studies financed by the U. S. Army; and the tropical medicine course for U. S. Navy physicians. Most of the smaller projects mentioned in 1985 are also still being pursued.

I emphasized last year, also, that it is our job, as managers of a small research enterprise, to make certain that we utilize our basic core funding to allow work to proceed on meritorious projects that are not receiving outside funds because of the vicissitudes of the funding systems or because it is necessary for us to maintain competence in areas of science that are not on the cutting edge of new concepts and technology but that are nevertheless important in monitoring disease spread and in providing basic data for new explorations. I pointed out that we had one project in arbovirology that we were supporting because we considered it valuable to continue even though it was in the category of "approved but unfunded" by NIH. This year, that project has been funded by NIH, and we are justified in having maintained it earlier. We are continuing to support modestly a project in acute respiratory disease. Our judgement of the value of this project has just been reinforced by a lead editorial in the January, 1986 issue of the American Journal of Tropical Medicine and Hygiene, entitled "Acute Respiratory Infections are the Leading Cause of Death in Children in Developing Countries."

We have, in accordance with recommendations by OTA and GAO, expanded involvement of our Advisory Scientific Board (ASB) in scientific direction of GML. After an early August, 1986 site visit by specialists in epidemiology and virology, we held a full-day meeting of ASB members in late August to review both the report of that visit and of the parasitology site visit held in November, 1984. This was the first time that GMI has convened the ASB at its own expense for an entire day of discussion. The minutes of that meeting were submitted to the Congress as appendix D in the last Annual Report of the Gorgas Memorial Institute provided on April 1st.

You have already been informed of the general agreement GMI has with the University of Alabama at Birmingham. In efforts to develop specific collaborative projects, the new President of the Gorgas Memorial Institute and I traveled to Birmingham in January to explore areas of possible mutual interest, in discussions with the scientists in the School of Medicine and the School of Public Health. A GML scientist is about to visit Birmingham to discuss one possible project.

In recent discussions with the Dean of the Faculty of Medicine of the University of Panama, Dr. Gaspar García de Paredes, we have agreed to cooperate with that institution in the development of their new School of Public Health, to the extent of providing some of their students with laboratory and/or field experience in their fulfillment of the requirements for a Master's Degree in Public Health. It is my understanding that the creation of a School of Public Health has been a desideratum of many professional individuals in Panama concerned with preventive medicine. I have also been told by Dr. García de Paredes that the Cuban Institute of Tropical Medicine has been advertising for students from Panama. GML will welcome the new students to the extent that we are able to do so. We expect that it will be to our mutual advantage.

I have already mentioned that GMI has a new President. In accordance with changes in our by-laws enacted in 1984, on the basis of the recommendations in the OTA and GAO reports, GMI has separated the offices of President and Chairman of the Board. The President is a paid, full-time officer of the Institute: the Chairmanship remains a pro-bono, unpaid position. The President is with me today. He is James H. Marchbank. He is charged with improving the management of both the Institute and the Laboratory, and of developing fund-raising materials and prospects. In the latter enterprise, the Chairman and other members of the Board of Directors expect to participate.

However, the prospects of fund-raising are still nebulous. Our fund-raising consultants advised on our applying for support for individual projects. On that score we do relatively well, as I pointed out last year. What we need is funding for renovating and building more physical plant, for special equipment, and for endowments of chairs and fellowships. These are large sums and we will have to work very hard to get them. Our President will have to demonstrate that we are a well-run enterprise, and that we merit contributions for growth and further development - not merely for staying alive.

For staying alive, Mr. Chairman, we must still rely on the Congress of the United States. A remote institution such as the Gorgas Memorial Laboratory, requires a core of support on which it can depend, and then it can seek individual project support, which we have been able to do in the last few years. We are grateful for the wisdom of the Congress in maintaining us during recent very difficult times, and to the Government of Panama for the large loan which their

Social Security Administration made to us in 1983, and for the direct annual financial contribution and special tax exemptions provided to GML.

Just when the GMI/GML have the possibility of achieving stability and of growing, we are now confronted with cuts in basic support. We have already been informed that we will lose $86,000 from our F.Y. 1986 funds because of the automatic rescission called for in the recently enacted deficit-reduction legislation. If further cuts are demanded, we will be back again at the brink of disaster. We had already dissected the fat - and unfortunately some flesh as well - out of our organization before the $86,000 rescission. Further cuts, if they occur, will take only flesh and will be disastrous to the continued operation of an important outpost of the U. S. biomedical research and training enterprise. We request restoration of the entire original appropriation for F.Y. 1987.

Thank you very much.

Biography of Dr. Leon Jacobs

Address and Telephone Number:

Home: 3705 Morrison Street, N.W.
Washington, D.C. 20015

Phone: 202/966-2674

Date and Place of Birth:

March 26, 1915
Brooklyn, New York

Educational Background:

Boys High School Brooklyn, New York		1927-1931
Brooklyn College Brooklyn, New York	B.A.	1931-1935
George Washington University Washington, D.C.	M.A.	1936-1938
George Washington University Washington, D.C.	Ph.D.	1939-1943 1946-1947
Tissue Culture Course, Mary Imogene Bassett Hospital, Cooperstown, New York		7/49-9/49
Course in Virology, U.S. Department of Agriculture Graduate School, Washington, D.C.		1949
Course in Ophthalmic Pathology, Armed Forces Institute of Pathology, Washington, D.C.		2/9-13/53
Course in Pathology, U.S. Department of Agriculture Graduate School, Washington, D.C.		1953
Course in Veterinary Pathology, Armed Forces Institute of Pathology, Washington, D.C.		1959

Professional Experience:

- **Junior Nematologist to Protozoologist, Division of Zoology, NIH**
- United States Army
- Protozoologist to Scientist Director, NIAID, NIH
- Head, Section of Protozoal Diseases, Laboratory of Tropical Diseases, NIAID, NIH
- Chief, Laboratory of Parasitic Diseases, NIAID, NIH
- Acting Scientific Director, NIAID, NIH
- Scientific Director, DBS, NIH
- Deputy Assistant Secretary for Science, DHEW
- Assistant Director for Collaborative Research, NIH
- Associate Director for Collaborative Research, NIH
- Director, Fogarty International Center, NIH
- Visiting Prof. of Microbiology, University of Arizona Medical School
- Visiting Prof. of Microbiology, University of So. Florida Medical School
- Scientific Director, National Society for Medical Research, Washington, D.C.
- Scientific Consultant, National Society for Medical Research, Washington, D.C.

Membership in Scientific Societies:

- American Society of Tropical Medicine and Hygiene
  - Editor, *Tropical Medicine News*
  - Representative to National Research Council
  - Council
  - Vice President
- American Society of Parasitologists
  - Editor, *Journal of Parasitology*
  - Chairman, Committee on Business Operations
  - Council
  - President
- American Association of Immunologists
- Helminthological Society of Washington, President
- Tropical Medicine Society of Washington, President
- Society of Protozoologists
- **American Association for the Advancement of Science**
- **Sigma Xi**
- **New York Academy of Sciences**

Research Interests:

Cultivation, epidemiology, and pathogenicity of parasitic protozoa; immunology and serology of protozoan and helminthic infections. Particularly interested in toxoplasmosis (life cycle and epidemiology, immunity, diagnostic procedures, ocular and other clinical manifestations and serology.)

Professional Publications:

Bibliography attached.

Other Activities:

Lectures at Johns Hopkins University School of Hygiene and Public Health	1956-present
Lectures at Georgetown University Medical School	1965-1968
Lectures and laboratory teaching of parasitology at Western Reserve University Medical School	1954-1958
Representative of the American Society of Tropical Medicine and Hygiene to the National Research Council	1957-1961
Consultant, Committee on Uveitis, American Academy of Ophthalmology and Otolaryngology	1957-1958
Chairman, Committee on Cooperative Publication, Conference of Biological Editors	1958-1960
Director and member of Executive Committee, Gorgas Memorial Institute	1969-1979
Chairman, Toxoplasmosis Sessions, 7th International Congresses on Tropical Medicine and Malaria	1963
Member, Executive Committee, Commissioned Officers Association of the U.S. Public Health Service	6/65
Member, WHO Expert Panel on Parasitic Diseases	
Chairman, Panel on Parasitic Diseases, U.S.-Japan Cooperative Medical Science Program	1965-1970
Member, Microbiology Subcommittee, Safe Drinking Water Committee, National Academy of Sciences	1976-1977
Chairman, Subcommittee on Research, U.S-Egypt Joint Health Working Group	1977-1979
Member, Board of Directors, Gorgas Memorial Institute of Tropical and Preventive Medicine, Incorporated	1969-
President and Chairman of the Board, Gorgas Memorial Institute of Tropical and Preventive Medicine, Incorporated	1983-
Adjunct Professor of Preventive Medicine, USUHS	1985-

Honors and Awards:

Army Commendation Ribbon	1945
Past President, Helminthological Society of Washington	
Biological Sciences Award of the Washington Academy of Sciences	1954
Arthur S. Flemming Award of the Junior Chamber of Commerce	1954
Brooklyn College Distinguished Alumnus Award	1955
Barnett Cohen Award, Maryland Society of Bacteriologists	1956
Fulbright Research Scholarship	1960-1961
Guggenheim Fellowship	1960-1961
Council, American Society of Parasitologists	1963-1966

Henry Baldwin Ward Medal of the American Society of Parasitologists	1963
George Washington University Alumni Achievement Award	1967
Distinguished Service Medal, USPHS	1966
Superior Service Award, DHEW	1968
Vice President, American Society of Tropical Medicine & Hygiene	1970
President, American Society of Parasitologists	1978

Senator BURDICK. Thank you very much. This is a strange question, but would you send a friend or relative down to that area without some kind of innoculations?

Dr. WEBB. We recommend the yellow fever vaccine, of course, for everyone who goes to that area, although the disease is held well in check, ordinarily. It's held in check by vaccination.

Other than that, the heritage of General Gorgas has left Panama and the Canal Zone itself a very safe place. It's a very healthy place to be. It demonstrates what preventive medicine is able to do; to create a healthful environment out of what once was a graveyard, you might say.

Somebody said of the French that the diseases aren't so bad down there; they only killed about 25 percent of the people that the French sent there. That was before——

Senator BURDICK. The same gain they made in Central America and Mexico.

Dr. WEBB. They have been made in many countries. This has to be maintained, you have to keep at it all the time. You don't just set it up and let it stay there. The least little relaxation and malaria will come back to the zone, as it did when I was down there in the Air Force.

So there's a lot to be done in tropical medicine and in preventive medicine and we'd like to do more of it at the Gorgas Institute.

Senator BURDICK. Well, thank you very much.

STATEMENT OF DAVID CALKINS, M.D., CHAIRMAN, HEALTH POLICY COMMITTEE, SOCIETY FOR RESEARCH AND EDUCATION IN PRIMARY CARE INTERNAL MEDICINE

Senator BURDICK. Our next witness will be Dr. David Calkins, chairman of the health policy committee, Society for Research and Education in Primary Care Internal Medicine.

Dr. CALKINS. My name is David Calkins, I am a general internest at the Beth Israel Hospital on Harvard Medical School in Boston, MA, and chairman of the health policy committee of the Society for Research and Education in Primary Care Internal Medicine, or SREPCIM.

SREPCIM was founded in 1978 as an affiliate of the American College of Physicians, and one of our major purposes is to promote the training of physicians in general internal medicine.

As you are aware, the administration's 1987 budget would eliminate all Federal funding for training grants in general internal medicine and other primary care disciplines. The rationale offered is that overall physician supply is excessive. While we do not challenge the projection of an overall physician surplus, we do take issue with the recommendation that Federal support for primary care training be eliminated.

The supply of primary care physicians is not excessive. Today, only 35 percent of physicians are in the primary care fields of general internal medicine, general pediatrics, and family medicine, which is far less than the goal of 50 percent recommended by the Institute of Medicine and others. In addition, there is increasing evidence that more primary care physicians can mean less costly health care.

The training grants in general internal medicine and general pediatrics support a new kind of residency training which emphasizes cost-effective health care. More than 25 percent of teaching in these programs takes place in an ambulatory setting, in contrast to only 10 percent in traditional internal medicine programs. Residents in general internal medicine learn skills in areas such as psychiatry and orthopedics and gynecology which are not included in traditional programs, and which allow these residents to manage the majority of patients without referrals to subspecialists.

Perhaps most important, these programs encourage residents to maintain a career in primary care. A survey of federally funded general internal medicine programs conducted last year by SREPCIM showed that 87 percent of program graduates have chosen careers in primary care. This is in contrast to only about one-third of the graduates of traditional internal medicine programs.

While the principal purpose of the training grants has been to support residency training, they also have allowed the development of faculty divisions of general internal medicine. A 1984 survey by our organization showed that 145 medical schools now have such divisions, and the faculty who staff them play a critical role in the hospitals and medical schools. They have improved the quality of patient care in hospital-based clinics, they have allowed residents to learn how to manage patients more efficiently in hospital settings, and they have served as important role models for medical students, interns, and residents, encouraging many to choose a career in primary care.

The development of these training programs would not have been possible without Federal support, and the need for this support continues today.

SREPCIM, therefore, would like to recommend that you maintain funding for training grants in general internal medicine, general pediatrics, and family medicine. In the case of general internal medicine and general pediatrics, we recommend an appropriation of $18.5 million, which is the same amount you appropriated last year and the prior year. Your past investment in these programs has paid off, and we believe that your continued support is necessary.

Thank you very much.

PREPARED STATEMENT

Senator BURDICK. Thank you very much.

[The statement follows:]

STATEMENT OF DAVID CALKINS

I am pleased to have this opportunity to present testimony on the fiscal year (FY) 1987 appropriation for the Department of Health and Human Services on behalf of SREPCIM — the Society for Research and Education in Primary Care Internal Medicine. SREPCIM was founded in 1978 as an affiliate of the American College of Physicians. Our major purpose is to promote the training of physicians in primary care or general internal medicine. Most of our members, who now number over 1300, serve on medical school faculties, and many are involved in the teaching of residents in general internal medicine. Accordingly, SREPCIM is especially interested in the appropriation for training grants in general internal medicine and general pediatrics, and I will confine my remarks today primarily to this aspect of the HHS budget.

Last year you and your collegues in the House appropriated $18.5 million for training grants in general internal medicine and general pediatrics. This sum subsequently was reduced to $17.7 million by the initial Gramm-Rudman sequestration. As a result of the Gramm-Rudman cut HHS will be able to fund only five or six new and competing renewal awards for residency training in FY 1986. HHS has received 31 applications for such awards. Though the review process is not yet complete, it appears that more than half of the approved applications will go unfunded. Furthermore, HHS will be unable to make any new awards for faculty development in general internal medicine and general pediatrics. As SREPCIM has testified in the past, we badly need more trained faculty in this field.

While the effect of Gramm-Rudman has been bad enough, the effect of the Administration's FY 1987 budget proposal would be much worse. As you are aware, the Administration's FY 1987 budget would eliminate all funding for training in general internal medicine and general pediatrics. The rationale offered is that overall physician supply is now or soon will be excessive. While SREPCIM does not challenge the projection of an overall physician surplus, we do take issue with the conclusion that federal support for general internal medicine and general pediatrics training should be eliminated. The supply of primary care physicians is not excessive. Today, only 35 percent of physicians are in the primary care fields of general internal medicine, general pediatrics, and family medicine, far less than the goal of 50 percent recommended by the Institute of Medicine and others. More primary care physicians are needed to improve access to basic health care services. Furthermore, there is increasing evidence, some of which I will cite in my testimony today, that an expanded supply of primary care physicians could mean less costly health care, a goal we all share.

The central purpose of the training grants in general internal medicine and general pediatrics is the support of a new kind of residency training, training which prepares young physicians to deliver high quality, cost-effective primary care services. Let me describe briefly the content of residency training in general internal medicine.

General internal medicine training differs from traditional internal medicine training in several important ways:

- More teaching occurs in an ambulatory setting. In a traditional internal medicine residency, about 10 percent of a resident's experience is in an ambulatory setting. In the general internal medicine programs supported by federal training grants, more than 25 percent of training takes place in such settings.

- General internal medicine programs emphasize continuity of care, as well as care which is comprehensive. Residents in these programs acquire skills in areas such as psychiatry, orthopedics, and gynecology, areas which are not part of traditional internal medicine training. Thus, they are able to manage the vast majority of problems encountered in ambulatory adult patients without referrals to subspecialists.

- Residents are taught principles of health maintenance. They work with other health professionals, including nutritionists and nurse practitioners, to counsel patients regarding diet, exercise, and other health-related behaviors. Thus, general internal medicine residents are able to help patients stay healthy as well as treat them when they are ill.

- General internal medicine training emphasizes cost-effective approaches to health care. Residents learn when to use laboratory tests as well as when not to use them. They also learn that many medical problems can be managed on an ambulatory basis, avoiding the need for expensive hospitalization.

STATEMENT OF PHIN COHEN

NIH grants are being misused by universities on a grand scale. The misuse has been going on for decades, is deliberate and is now so habitual as to be indigenous to the system.

There are 2 groups who know of the misuse: Middle level Federal auditors who do the shirtsleeve work on the audits of grants management by universities, and principal investigators (PIs) who do the shirtsleeve work of grant applications and then are hampered in their research when their grants are plundered at various levels in the universities. This subcommittee rarely hears from either group.

I was a PI whose grants were plundered by Harvard University. I'll tell you my story in outline form:

1. I won 2 NIH grants in 1971. Almost immediately, the Department of Nutrition, Harvard School of Public Health, (HSPH) began to divert the money of those grants. I complained to the Department of Nutrition, and then to the Assistant Dean of Finances. The problem persisted.

2. In 1975, not able to resolve the matter within my department or school, I complained to the central administration of Harvard University about the grants mismanagement and asked for an audit of grants of all PIs in the Department of Nutrition. This was not done. I was labelled paranoid and terminated, only 8 months after an ad hoc committee had unanimously recommended me for a promotion with a 5-year term.

3. In December 1975, I reported to the NIH in Bethesda that money from my hardwon grants had been diverted by Harvard and that the problem possibly was wide-spread.

4. In the Spring of 1976, an audit by the Division of Management Survey and Review (DMSR), of the NIH found that my grants had, in fact, been plundered by Harvard. The bottom line of that limited audit was 132 Thousand Dollars, which Harvard paid to the federal government penny for penny.

5. In June 1976, the Director of the DMSR, believing that

academic general internist offers trainees, including those in traditional internal medicine programs, an alternative.

The development of general internal medicine residency programs and faculty divisionis of general internal medicine would not have been possible without federal grant support. Our current practices of paying physicians and hospitals encourage the development of faculties dominated by subspecialists and residency training programs focused on technology-intensive inpatient services. By explicitly funding ambulatory care teaching, the residency training grants have provided departments of medicine with an incentive to add to their ranks faculty interested in general medicine and residents whose training includes substantial ambulatory care.

During the mid-1970's this Committee saw the need for an expansion in the supply of primary care physicians. You responded by funding grants for residency training in general internal medicine and general pediatrics, as well as family medicine. The need for more primary care physicians continues today, and in some sense is even more acute given the rising cost of health care. SREPCIM urges you to maintain funding for training in general internal medicine and general pediatrics, as well as family medicine. In the case of general internal medicine and general pediatrics, we recommend an appropriation of $18.5 million, an amount equal to that appropriated in FY 1985 and 1986. We believe this appropriation would allow for the full funding of approved residency programs and the renewal of a program in faculty development. Your past investment in these activities has paid off. Your continued support is needed.

Thank you again for this opportunity to present our views.

STATEMENT OF PHIN COHEN, M.D., SCIENTIST/PHYSICIAN

Senator BURDICK. Our next witness is Dr. Phin Cohen, scientist/physician.

Dr. COHEN. Thank you, Senator. I am here to speak on grants mismanagement, a topic which I doubt is frequently aired in this room.

In early 1975 when I complained to the central administration at Harvard that my NIH grants were being mismanaged, I was labeled paranoid and terminated only 8 months after an ad hoc committee had unanimously recommended me for a promotion with a 5-year term.

In late 1975, I reported the problem to the National Institutes of Health in Bethesda. In the spring of 1976, NIH auditors found that my grants had been plundered and recommended that Harvard pay back $132,000 to the Federal Government and that a general audit be done at Harvard. The Department of Health, Education and Welfare sat on this request for a general audit.

In April 1977, I filed a complaint in Federal court asking, among other things, that the court order an audit of Harvard. The audit took 7 years to complete. Please refer to my written testimony for the wording of two key paragraphs of my complaint, and then compare the wording with the results of the audit. Paragraph 44.

With respect to direct costs, I predicted that a general audit would show widepsread and large-scale misuse of Federal awards involving millions of dollars. In 1983, Harvard settled in the amount of $4.6 million for misspent direct costs, the largest settlement by far in the area of direct cost in the history of Federal audits at universities. Paragraph 45.

With respect to indirect costs, I predicted that Harvard knowingly misused and misappropriated indirect costs with the same disregard for Federal law and regulations as with direct costs. In 1984, Harvard settled with HHS in the amount of $10 million for misspent indirect costs, the largest settlement by far in the area of indirect cost audits at universities.

The usual excuse that universities give for such misspending is sloppy bookkeeping, but it turns out that Harvard knew what was being done was wrong, but did it anyway. Let me quote from two internal memoranda from the assistant dean of finances to the dean of the Harvard School of Public Health to put to rest the excuse of sloppy bookkeeping.

First, I quote from a memo which admits deliberate diversions of money.

> The teaching programs benefit from diversion of Federal funds which redounds to the benefit of the school of public health financial results. A certain portion of the salaries and fringe benefits of faculty supported by Federal research funds is, in fact, diverted into the teaching programs. This ploy has double dividends; it not only enriches the catalog offerings, but it also tends to overstate the size of the indirect cost pool * * *."

Next, I quote from a memorandum in 1973 which admits to deliberate duplications of cost at the departmental administration level.

> Each little duchy has its own duplicate set of super-secretary-administrators, bookkeepers, lesser secretaries, and a manner of living replete with department kitchens and a sense of homey gemutlichkeit.

These quotes are not academic chit-chat from an absentminded professor to a colleague about some arcane scientific matter. This is a person in charge writing to another person in charge about diversions of money on the one hand and duplications of costs on the other. If a weapons manufacturer wrote memoranda like these and the subcommittee became aware of them, it would be labeled fraud.

With respect to indirect costs I again quote verbatim, first from a report released in December 1985 by the Inspector General, HHS, which included data from 12 universities, Harvard among them.

"In fiscal 1984 over $330 million of such payments—for the departmental administrative component of indirect costs—did not benefit Government-sponsored research." In this context, recall the quote I read 1 minute ago about duplicate sets of secretaries and bookkeepers.

Next, I quote from a letter by a Federal official about the Harvard audit.

> It is a situation where Harvard failed to provide data in its indirect cost proposals to the Government, and after many years has perpetually and continually refused to provide the data * * * Harvard itself has acknowledged that its records were not maintained so as to permit audits * * * For those years in which Harvard knowingly and purposely omitted data, despite being on notice that the Government required the data, the action is known as stonewalling * * *."

These are pretty strong words. I am no longer speaking of allegations of 1977; I am speaking of the facts which have piled up inexorably since 1977. However, I'd be disingenuous to leave you with the impression that the problem is confined to Harvard. It is a nationwide problem. I have thoroughly read 125 audits of universities in all sections of the country, and this is in my written testimony.

In closing, NIH grants are being misused by universities brazenly and on a grand scale. The misuse is deliberate and is now so habitual as to be indigenous to the system. As a person whose prophecies of 1977 have come to pass in ways and on a scale that few would have dreamed possible, I now have the platform to earnestly request that the subcommittee thoroughly read my written testimony and consider the serious nature of its contents.

Senator INOUYE [presiding]. Thank you very much, doctor. Have you discussed this matter with NIH and HHS?

Dr. COHEN. Yes; I have.

Senator INOUYE. What were the results of your discussion?

Dr. COHEN. Well, the discussion with NIH in 1975 precipitated the NIH audit of 1976. Discussions were held in 1977 with HHS auditors, in which I said what I thought they would find and where they could find it.

Senator INOUYE. Was there any followup from these audits?

Dr. COHEN. The followup is $15 million so far have been recovered, which is more than was recovered in the entire fiscal 1977 from all the universities in the Nation. It is a recordbreaking audit in terms of the bottom line.

PREPARED STATEMENTS

Senator INOUYE. I can assure you that we will read your testimony, sir. Thank you very much. Your statement will be included in the record at this point along with other statements submitted for the record on appropriations for the National Institutes of Health.

[The statements follow:]

Perhaps most important, residents in these programs learn through experience and example that a career in primary care can be intellectually and personally rewarding -- and they stay with it. A survey of federally funded general internal medicine residency programs conducted last year by SREPCIM shows that 87 percent of residents trained in these programs choose careers in primary care. In contrast, only a third of the graduates of traditional internal medicine programs choose such careers.

While the principal purpose of the training grants has been to support the education of general internal medicine residents, they have had other desirable effects. They have been a major stimulus to the development of divisions of general internal medicine throughout the United States. A 1984 SREPCIM study shows that there are now 145 divisions or sections of general internal medicine in U.S. medical schools. The faculty who staff these divisions play a critical role within their hospitals and medical schools:

- Faculty in divisions of general internal medicine spend almost half their time in direct patient care, ususally in hospital-based clinics or group practices. These clinics are an important source of ambulatory care, especially for the poor. The presence of full-time faculty in such clinics has led to improvements in both the quality and efficiency of services.

- Faculty in divisions of general internal medicine spend about a third of their time teaching in ambulatory and inpatient settings. They supervise residents in traditional internal medicine programs as well as those in primary care. General medicine faculty train residents in health promotion and disease prevention, as well as cost-effective approaches to health care. Studies show that residents use hospital resources more efficiently when they are supervised by faculty in general internal medicine than when they are supervised by subspecialists.

- General internal medicine faculty serve as important role models for medical students, interns, and residents. Research indicates that medical school faculty have a significant influence on the career choice of physicians in training. The dominant role model on most medical school faculties is the subspecialist. The

the practices of the Department of Nutrition were possibly wide-spread at Harvard, asked the then-HEW audit agency to do a general audit of federal grants management at all schools at Harvard. The audit agency shelved this request, according to internal documents which I later obtained.

6. In April 1977, I filed a complaint in Federal Court asking, among other things, that the Court order an audit of Harvard. A copy of the complaint was mailed to the United States Attorney General, who forwarded it to officials at HEW.

7. As of June 1977, there were apparently no plans for an audit. I then raised a fuss in Washington which finally precipated the audit which began in September 1977.

8. The audit took over 7 years to complete. Let's compare the results of various phases of that audit with the wording of 3 paragraphs of the complaint which I filed in April 1977:

Para 44: "Based upon information and belief, it is alleged that a general audit of federal grants and contracts at Harvard would show wide-spread and large-scale misuse of federal awards, for the relevant period, as well as many preceding years, involving millions of dollars. These improprieties derived from Harvard's unlawful and illegal acceptance of the fungibility of direct cost awards. Harvard has knowingly permitted and fostered pooling, fungibility and arbitrary and illegal allocation of direct costs. This attitude has resulted in wide-spread and large-scale and illegal distribution of direct costs in contravention of federal law, regulations and policies and violates the spirit and intent of the peer review system."

In 1983, Harvard settled with the federal government in the amount of 4.6 Million Dollars for misspent direct costs, by far the largest settlement in the area of direct costs in the history of HEW/HHS audits of grants management by universities.

Para 45: "Based upon information and belief, Harvard knowingly misused, misappropriated and sequestered indirect costs with the same disregard for federal law, regulations, and policies. For the relevant and presently undefined preceding period, Harvard treated all indirect costs from federal awards as allocable to fiscal obligations without due regard to whether those obligations derived from 'benefiting activities.' During the period 1970-1976, Harvard applied for, negotiated for, and received approximately One Hundred Million Dollars in indirect cost awards in connection with federal grants and contracts, of which approximately forty percent was awarded to the medical area in Boston. By sequestration and misappropriation of these indirect costs, Harvard violated federal laws, regulations, and policies, and also denied the rights of and hampered the scientific pursuits of principal investigators whose work would have benefited from all of the support that their indirect cost awards were supposed to have provided."

In 1984, Harvard settled with the federal government in the amount of 10 Million Dollars for misspent indirect costs, by far the largest settlement in the area of indirect costs in the history of HEW/HHS audits of grants management by universities.

What began as a defense of my own grants grew to huge proportions. The bottom line, approximately 15 Million Dollars, exceeded the combined bottom lines of all audits at all universities in 1976-1977. I know because I've read all of those audits. I ask now, with reference to the calumny heaped upon me by Harvard as a result of my dissent: What is the antonym of paranoia?

Para 60: "During the period 1970-1976 Harvard for the purpose of obtaining or aiding in the obtaining of payment of its expenditures in connection with awards received from the United States and agencies, departments and officers thereof, did make, use and cause to be made and used false vouchers and reports of expenditures knowing the same to contain false, fictitious and fraudulent statements in that all of the expenditures reported were not made in connection with the designated awards as the defendants well knew when they filed the reports and vouchers."

Harvard knew what was being done was wrong, but did it anyway. I quote from a remarkable internal memorandum from the Assistant Dean of Finances to the Dean of HSPH, which was written in 1975 while mincemeat was being made of my career and reputation by the very perpetrators of the wrongdoing.

"The teaching programs benefit from. . .diversion of federal funds which redounds to the benefit of School of Public Health financial results. A certain portion of the salaries and fringe benefits of faculty supported by federal research funds is in fact diverted into the teaching programs. This ploy has double dividends. It not only enriches the catalog offerings available to tuition-paying students (i.e. unrestricted income) but it also tends to overstate the size of the federal indirect cost pool. . ."

"The point of this extended discussion of the possible origins of the School's operating surpluses is to underline the fragile and transitory nature of the many factors involved. . . The Harvard School of Public Health will be unable continuously to tap the till of overallocated research costs. Should federal frank support of teaching stumble and covert support diverted from research faculty dwindle, unrestricted costs for educational programs could suddenly multiply. . ."

(The emphasis supplied in the above two paragraphs is mine)

When "covert" support is "diverted" from research faculty (PIs) by a "ploy," false vouchers have to be filed. "Covert" and "diverted" are muscular words which are handmaidens to fraud on the one hand, and the deprivation of academic freedom of PIs on the other.

This same Dean of Finances, while refusing to provide information to me about my grants, knew that what he and the Dean (the Chief Financial Officer according to Harvard's statutes) were doing was blatantly illegal. My termination by Harvard was a typical reaction by corporate leaders towards dissenters, and sent a chilling message to other PIs: Complain about our mismanagement of your funds and you will be fired. When money is at stake, the academic freedom and collegiality which your committee hears so eloquently phrased by college presidents, deans, department chairmen, and Nobel Laureates, goes out the window. Bare knuckles university science politics is at its worst when it comes to questions about the misuse of money that your committee appropriates and the principal investigators win.

The problems are not confined to Harvard, however. They are national in scope.

With respect to direct costs, I've read 125 audits of direct costs at universities throughout the country. The misspending of federal grants covers all categories of expenditures, and is creative as well as deliberate and purposeful. I offer selected quotes from various audits:

1. The accounting office directed in writing that cost overruns be eliminated by journal transfers.
2. Salaries were recovered twice, once each from both direct and indirect costs.
3. There was excessive federal contribution to an unemployment compensation fund "so as to create a contingency reserve."
4. There was improper withholding of social security taxes.
5. There was overbilling of federal grants for medical insurance.
6. The university kept unclaimed checks.
7. The university retained student aid money for students who did not matriculate.

These are not the mistakes of absent-minded professors or feckless bookkeepers. These are the machinations of university finance officers to convert nondiscretionary money to discretionary money without regard to legality or the beneficiality to science. The principal motivation is institutional greed. The PIs raise the money, the universities deliberately mismanage it and the PIs better damn well not complain about it. That's the situation. The PIs need your help. They are the heart of the biomedical enterprise. They have many responsibilities but no rights. If they cheat with money or data they can expect federal wrath, and, indeed, deserve it. But when their grants are plundered and they are fired for complaining about it, they have no federal protection. This is an awful situation which you could remedy with a rider to an appropriations bill to protect PIs who defend their own grants from plundering.

With respect to indirect costs, I refer you to a report released in December 1985 by the Inspector General HHS. I quote from that report:

". . .We identified an opportunity to contain these costs" (indirect costs) "and make $255 million available annually, or about $1.3 billion over a 5-year period, to meet other budgetary needs of the Government, including the financing of thousands of unfunded research projects already approved for technical merit."

". . .in fiscal year 1984 over 300 million of such payments" (for the Departmental Administrative component of indirect costs) "did not benefit Government sponsored research."

I again refer you to paragraph 45 of my complaint. The key words are "benefiting activities," and the key actions by universities are to divert monies from "benefiting activities" to discretionary funds for purposes which the shirtsleeve auditors well know are not connected to science. When defense contractors divert monies this way the government reacts harshly. Diversion by weapons manufacturers is prosecutable. Diversion by universities is a lesser offense because universities are supposed to be above venal motivation; therefore, any diversions must be due to bad bookkeeping. Let me close with some quotes to further put the misconception of bad bookkeeping to rest.

In 1973, a memorandum, also from the Assistant Dean of Finances to the Dean of the HSPH, contained the following:

"Each little duchy" (referring to each department) "has its own duplicate set of super-secretary-administrators, bookkeepers, lesser secretaries, and a manner of living replete with department kitchens and a sense of homey gemütlichkeit"

This is not an absent-minded professor writing to a colleague about some arcane scientific matter. This is a person in-charge writing to another person in-charge about duplications of costs in the very area, departmental administration, where the Inspector General HHS wants to save money.

Finally, in a letter about the indirect cost audit at Harvard a federal official wrote:

". . .it is a situation where Harvard failed to provide data in its proposals to the government and after many years has perpetually and continually refused to provide the data."

". . .Harvard itself has acknowledged that its record were not maintained so as to permit audit. . . ."

". . .for those years in which Harvard knowingly and purposely omitted data, despite being on notice that the government required the data, the action is known as stonewalling. . ."

These strong words speak for themselves.

We are no longer speaking of my allegations of 1977. We are speaking of the facts which have piled up inexorably since 1977. The facts support my dissent most eloquently.

NIH grants are being misused by universities on a grand scale. The misuse has been going on for decades, is deliberate and is now so habitual as to be indigenous to the system. The PI who tries to defend his hardwon grants is twice a victim: first, he loses his grants; then, his career.

STATEMENTS OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) wishes to submit the following comments on the President's proposed Fiscal Year (FY) 1987 budget for the National Institutes of Health (NIH). The ASM is the largest single biological life science society in the world with an active membership of over 34,000. Many of these individuals are engaged in biomedical research and are recipients of awards administered by the NIH.

The ASM considers federal support for fundamental research to be of the highest priority for the national well-being and security. We are encouraged by the generally positive approach to enhancing funding for such research to be found in the President's overall budget request for science in FY 1987. However, we are especially distressed to note that the NIH has been singled out for a significant decrease in its proposed budget. This decrease is counter to the recommendations of those officials within the Administration who have professional responsibility at the scientific level for administration of the NIH. In view of the critical role of the NIH in fundamental health-related research and at the cutting edge of biotechnology, we support the budget recommended by the Ad Hoc Group for Medical Research Funding as a minimum acceptable increase for NIH. This proposed budget takes into account both the current fiscal restraints and the scientific significance of the research supported by the NIH. The proposal would bring the increase for the NIH into line with those requested by the President for science support in other agencies, excluding the large increase for the Department of Defense (DOD). The overall figure recommended by the Ad Hoc Group for FY 1987 is $6.079 billion, which represents the current services level of $5.993 billion and a very modest figure of $86 million, or 1.4%, for program growth.

Because it has been severely tempered by the stark realities of the current budgetary problems, the Ad Hoc Group's proposal does not advocate optimal funding for NIH. We, therefore, recommend that an additional $60 million over the Ad Hoc Group's bottomline figure of $6.079 billion could be efficiently deployed over a wide range of activities in the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of General Medical Sciences (NIGMS), and the National Institute of Dental Research (NIDR), all of which fund the major portion of research in microbiology. In addition to NIAID's taking the lead role in research on Acquired Immune Deficiency Syndrome (AIDS), NIAID and NIGMS fund much of the original research in molecular genetics and immunology that is on the cutting edge of modern biology. The basic, untargeted research in the biomedical sciences supported by NIGMS is fundamental and provides the underpinning for all the disease-oriented research done by the other institutes. The NIGMS has sponsored much of the important research on recombinant DNA that is leading to direct payoffs such as the manufacture of important biological substances, including human growth hormone, insulin and interferon, the development of new vaccines against diseases that cause illness and death for millions of people, and the early diagnosis of certain genetic disorders. The NIAID is supporting exciting research on the immune system to learn more about its role in the development of chronic diseases such as cancer, arthritis and asthma. The NIAID is the main source of funding for research on infectious, immunologic and allergic diseases which account for nearly one-third of all visits to physicians. The NIDR supports essential research on carries and periodontal disease which are bacterial in origin and account for the most common infections in the nation costing billions of dollars annually for treatment. Infectious diseases as a group remain one of the major health problems of this country, resulting in approximately 27 million patient-days of acute hosptial care each year at an estimated cost of nearly $6 billion. Despite the fact that so much of the cutting edge fundamental science in NIH is sponsored by NIAID and NIGMS, these institutes continue to have some of the lowest paylines at NIH, reflecting the number of excellent research applications which they receive. This situation creates a special hardship for investigators supported by these institutes and important research efforts could be seriously impaired without additional funding.

We believe that it is essential to maintain the current pace of NIH support for research. Significant cutbacks of such support, even for a one-year period, would have a long-lasting effect and should be avoided if at all possible. Deferring research projects for even short periods of time can result in damaging effects that will be felt much later. Not only is research momentum lost, but research teams are disbanded and new research trainees cannot be attracted and retained. The instablilty and unpredictability associated with a stop-and-go pattern of funding for biomedical research results in losses in terms of time, personnel and costly start-ups of laboratories and retraining programs. Biomedical research is a long-term investment which should not be sacrificed in economically difficult times because it ultimately contributes not only to lower losses from sickness and death but also to more goods, more jobs and higher productivity.

In addition to our general concerns over the President's recommendations for FY 1987, we are dismayed by the increasing tendency of the Congress to provide funds that are inadequate to support the number of research grants which are mandated. Although we are pleased that the Senate Budget Resolution recommends that 6,000 new and competing grants be awarded by NIH in FY 1987, we are distraught that not enough of an increase may have been provided for the actual dollars required to support this number of grants. Because of chronic underfunding for basic biomedical research, and the effects of the Gramm-Rudman-Hollings cuts, both new and competing and noncompeting NIH grants are currently being paid at 10-15% below study section recommended levels. With the amount provided in the Senate Budget Resolution, this situation could be exacerbated in FY 1987. These cuts are of particular concern because they come on top of an already rigorous pruning that occurs during the peer review process in the study sections with respect to the direct cost part of the grant. This approach is intolerable in that grants are awarded to conduct specific research that cannot be done if the funds provided are inadequate. While we recommend that no fewer than 6,100 new and competing grants be awarded in FY 1987, we urge as strongly as we can that sufficient funds be allocated to adequately fund the number of grants mandated. To do otherwise would result in the further "downward negotiation" of the size of grants next year, and a point of diminishing returns in terms of research effort could be reached.

We are concerned by the suggestion from the Office of Management and Budget (OMB) that all funds designated for research on AIDS, including money to support noncompeting research activities as well as support for intramural scientists, be placed under the control of the Office of the Assistant Secretary for Health (OASH), rather than directly within the budgets of the individual institutes at NIH. We do not believe that the argument that says placing such funds in the OASH would enhance flexibility, is valid; rather, we suspect that such manipulation will actually result in a much less efficient use of money to support research into this critical area. It also represents a bad precedent for transferring funds for a specific disease out of NIH's research budget base. Under the conditions proposed, it becomes virtually impossible for the specific institutes, in particular the NIAID, to administer and maintain ongoing, meaningful programs of research into the prevention and treatment of AIDS. We strongly urge that funds for AIDS research be placed directly into the budgets of the individual institutes.

Second to none among our concerns is that at a time when there is already a perceived shortage of people trained in the area of biotechnology and an even greater decrease in the number of students matriculating into graduate programs in biology that the Administration suggests a virtual cessation of support for new graduate student training. This is a question of grave importance and the small amount of money to be saved is hardly worth the severe mortgaging of our future that it represents. We currently see a decline in the number of Ph.Ds matriculating into the biomedical sciences at a time when, scientifically speaking, we are in the midst of an explosion of research opportunities in the biomedical sciences that are unparalleled in history. In order to take advantage of these opportunities, we must make sure that we continue to train adequate numbers of qualified young men and women for careers in biomedical research. Acquiring the skills necessary to conduct basic biomedical research requires a minimum of 6 years on the job training (approximately 4 years predoctoral and 2 years postdoctoral after the baccalaureate degree). The Institute of Medicine (IOM) Committee on Personnel Needs and Training for Biomedical and Behavioral Research's most recent data shows a decline in bioscience Ph.D. production. The Committee wrote in its 1985 Report that the number of predoctoral trainees in the basic biomedical sciences supported in 1984 was 11% below the Committee's recommended level and "is on a steep downward slope." The Committee went on to state that in the next 5 years, a large number of faculty members will reach retirement and consequently the need for young faculty to replace them will begin to increase. The Committee further stated that National Research Service Award (NRSA) research training funds have declined since 1974, both in real terms and as a percentage of research expenditures, to a level below that previously recommended by the Committee. The Committee concluded by stating that the research training programs should be restored to the recommended number of positions by 1987 (12,825), and then adjusted to meet the increase in demand expected to begin in the late 1980s. The proposed budget of the Ad Hoc Group would enable a continuation of the funding of graduate education and support for new students.

We are concerned about the funding levels for two additional areas supported by the NIH Division of Research Resources (DRR), namely, Biomedical Research Support Grants (BRSG) and the Animal Facilities Improvement program. The President has recommended zero funding for the BRSG program in FY 1987. The amount appropriated for this program in FY 1986 was $62.6 million, which is a small amount of money compared to the enormous benefits of BRSG grants to medical schools, universities and colleges. These grants provide schools with the flexibility to support bright young men and women just starting in a research career and they play an important role in supporting established researchers who experience delays in funding. The BRSG grants prevent the closing down of research labs for short periods of time, and, more importantly, the costly start up when funding becomes available. The ASM recommends restoration of funding for BRSG support at the FY 1986 level. We also recommend at least an additional $10 million be added for the Animal Facilities Improvement program and $1 million to support the training of more laboratory animal veterinarians to meet the increasing demand created by new animal welfare policies. We strongly believe that Congress should provide the funds necessary for renovation and replacement of substandard animal facilities. According to a National Research Council survey, about 38% of all nonprofit biomedical research organizations have reported a need for remodeling their animal facilities and 16% need to replace them.

Finally, we are concerned, as are most other people involved in federal research, with the problem of determining indirect cost. Our concern is sufficient so that we have actually supported the effort of the Administration to place a one year cap of 26% on administrative costs. However, we are strongly opposed to the proposed decrease to 20% in FY 1987. We consider the number to have been arbitrarily determined. Rather, we favor an approach in which the recommendations on indirect costs of the Administration's own White House Science Council are taken into consideration and which would hopefully lead to more uniformity and equity in the determination of indirect costs rates at different institutions.

In summary, we consider the President's budget recommendation for NIH to be inadequate and severely harmful to the research potential of the nation. We urge you to increase the investment in the nation's basic health-related research effort at NIH to a level of at least $6.079 billion in FY 1987 and to consider the additional monies recommended for the NIAID, NIGMS, and NIDR. As expensive as research may be it is a bargain compared with the cost of disease. The funds involved represent a very small portion of the total health bill of the country, only 1.2% of a $456.4 billion expenditure, but are probably the key area if we ever hope to be successful in stabilizing health care costs. Health research is absolutely essential to the national interest and must be spared from short-term savings to deal with the current deficit crisis. The economy of the US benefits from the excellence of NIH supported basic research which is often the forerunner of applied technology. We must maintain our competitive edge in science to ensure a strong economy, and scientific research should be one of the nation's highest priorities.

We appreciate the opportunity to comment and stand ready to assist the Committee during the budget process for NIH.

The American Society for Microbiology (ASM) **wishes to submit the following comments for the record on the Fiscal Year (FY) 1987** budget for the Centers for Disease Control (CDC) for consideration by the Senate Subcommittee on Appropriations for Labor, Health and Human Services, Education and Related Agencies.

The ASM is the largest, single biological life science organization in the world with an active membership of approximately 34,000. Prominent among our members are those clinical and public health microbiologists, infectious disease specialists, physicians, epidemiologists, clinical laboratory scientists and public health officals whose primary responsibilities are to detect, control and treat infectious diseases. These activities not only hold infectious diseases in check and prevent epidemics, but they attain their larger purpose of maintaining a healthy nation and a capable workforce.

The ASM is of the firm opinion that the control of acute and chronic diseases must be part of a national policy and depends on well-funded, long-range programs of research and service to the entire population. We are very much concerned that the budget for FY 1986 has been revised downward to $415 million, reflecting a reduction of $20.1 million due to the Gramm-Rudman law. We are even more concerned that the Administration's budget request for FY 1987 of $380 million shows an additional reduction of $35 million from the revised FY 1986 budget for CDC. The total reduction for CDC taken over the fiscal years 1986 and 1987 would be $55 million. In our opinion, these reductions will have an adverse impact on the ability of the CDC to carry out its public charge to protect our country against infectious and non-infectious acute and chronic diseases. A review of the FY 1987 AIDS funding proposal, which is supposed to be consolidated in the Office of the Assistant Secretary of Health (OASH), indicates a cut of $12.4 million in the CDC allocation below the FY 1986 congressional appropriation. The rapid spread of AIDS in our communities, especially outside of the homosexual community, requires that the federal agencies, charged by the public with the protection of public health, must support the diagnosis and investigation of the devastating disease and must assist in the dissemination of information to all citizens. The CDC has made major contributions in research and diagnosis of AIDS and must continue and expand upon its efforts. In the March 14 "Morbidity and Mortality Weekly Report" it was recommended that "community health education programs should aimed at members of high-risk groups to: a) increase knowledge of AIDS; b) facilitate behavioral changes to reduce risks of HTLV-III/LAV infection; and c) encourage voluntary testing and counseling." The report further states that counseling and voluntary serologic testing for AIDS should be routinely offered to all persons at increased risk when they are present at health-care facilities. These facilities include sexually transmitted disease clinics, clinics for treating parenteral drug abusers, and clinics for examining prostitutes. We are opposed to reallocating CDC's AIDS funding to OASH because we believe such a transfer could be disruptive and could interfere with CDC's administrative ability to respond to new opportunities in the area of AIDS. We recommend that $12.4 million be restored to the FY 1987 budget. Another concern to microbiologists is the area of immunization. The budget request is $3 million less than the orginial FY 1986 congressional appropriations. How can the states perform an active vaccination program to keep up the excellent immunization status of our children if the budget is decreased rather than increased? Also, the Administration requested no funds for the vaccine stockpile. In light of the problems vaccine manufacturers are having in obtaining liability insurance, the present CDC stockpile of childhood vaccines, a 16 week emergency supply, is insufficient to protect the welfare of our children. This program should be expanded to assure the continued immunization coverage of all infants and children. During the past years, several vaccine manufacturers have discontinued the production of vaccines and given up their licenses; one major manufacturer is still licensed but does not produce vaccines; and the largest remaining manufacturer has problems with liablility insurance coverage. It is quite possible that in the near future no vaccine will be manufactured in the United States and the CDC's stockpile will be the only source for mass vaccination programs. Everybody remembers the sudden shortage of diphtheria-pertussis-tetanus vaccine a year ago and the tremendous concerns of the medical profession about the potential reappearance of deadly childhood diseases. In light of the serious difficulties U.S. vaccine manufacturers are experiencing, the CDC budget for aid to states in immunizaton programs must be supported to the fullest extent. Although the immunization status of infants and children at this time is exemplary due to the efforts of CDC, the situation can change rapidly if the small stockpile of childhood vaccines is exhausted. The budget allocation for immunization programs should be restored to $60 million.

In closing, we would like to address the problems posed by continued budget reductions for the Centers for Disease Control. Every country in the world, including developing countries, has a more or less well-supported national reference center for the diagnosis, investigation, and prevention of acute and chronic infectious diseases. A continued decline in the budget of the best national reference center in the world, CDC, will reduce its stature, lead to the loss of valuable experts, and have detrimental effects on disease control efforts on the federal, state and local levels. We do not believe the country can afford to have this happen. The CDC occupies a highly significant position as the only reference diagnostic center for this nation, working with its states and providing control efforts in the international setting.

We welcome this opportunity to express our thoughts and we are prepared to work with you in any way that may be useful. It is our intention only to address inadequacies and to help bring about budgetary changes as needed for the Centers for Disease Control to perform their assigned functions effectively, efficiently and economically in order to comply with their public charter to protect the health of our nation.

STATEMENTS OF CHARLES E. PUTMAN, M.D., VICE CHANCELLOR, HEALTH AFFAIRS, DUKE UNIVERSITY MEDICAL CENTER; VICE PROVOST, DUKE UNIVERSITY

I am Charles Putman, Vice Chancellor for Health Affairs of Duke University Medical Center, and Vice Provost of Duke University. I am extremely grateful for the privilege of representing the Society of Academic Radiology Chairmen and the Association of University Radiologists concerned with commitments to Biomedical Research, Education, and other health-related matters.

Radiology has experienced more dramatic changes in the past twenty years than any other specialty in the field of Medicine. Medical Imaging procedures account for, or contribute directly to, the final patient diagnosis in over seventy-five percent of all hospital admissions. In addition, Diagnostic Radiographic examinations, or more broadly stated medical uses of radiation, account for the vast majority of the human annual exposure to radioactive sources. Though representating one of the more innovative disciplines which is at the frontier of new Technologies expanding Basic and Clinical Research and with a unique and focused impact on the diagnosis and therapy of disabling and life-threatening diseases, I would like to forego parochial wisdom, and restrict any further comments to some of the generic concerns that the Research and Academic Health Care Centers are facing together.

Most of us are products of the goodwill, generosity and encouragement of the Federal granting process. We have been the benefactor of a system which has allowed educational loans for the training of fellows, acquisition of scientific equipment, and dollars to support Basic, Applied and Clinical Research Programs. We have with your immense help and the leadership of your sponsoring bodies [The National Institutes of Health] provided for our mutual constituency--the public--a system of intellectually honest, industrious, and sensitive scientists who struggle to solve the complexities of a myriad of diseases--whether it be through early detection, eradication, or by providing new and efficacious therapeutic interventions. At times our efforts seem to pale in comparison to our obstacles--whether it be Alzheimer's Disease, Acquired Immune Deficiency Syndrome, Malignancy, Arthritis, or Cardiovascular Disease. Yet by your own knowledge and experience, and through the expressions of other speakers before you, attest to our successes as well as to our limitations and challenges.

At times you may see us as an independent group of individuals, each representing a particular Institution, Private or Public with differing problems and solutions, an M.D. or a Ph.D. with differing roles and responsibilities, a bench researcher or a bedside clinician with perhaps opposing views and aims, a diagnostician or one principally trained for a therapeutic role, a generalist or someone very subspecialized. Our research may appear at times esoteric; at other times it would appear to be mundane. Too often it is true, we emphasize our passion for scientific success, adhering to the Disease-of-the-Month-Club syndrome. Though our efforts may appear to be fragmented, we share in common a commitment to the future generation of medical scientists and the responsibility to seek answers for those diseases that thus far have escaped our ability to diagnose and successfully treat.

The process of allocating public revenue, responding to the Federal deficit, and providing for the general safety and wellbeing of all American citizens does not need irrational or compromising recommendations from the scientific Medical Community.

The Process and the Challenges

In summary:

1. We must maintain the highest regard and respect for the peer review system. It has served the Biomedical Community and Public well, and should not be replaced by an arbitrary substitute, regardless of its best intention.

2. Educational allowances, regardless of the level, must be maintained and strengthened. Predoctoral and post-doctoral opportunities for present and future clinicians and scientists are the best investment for ultimately acquiring needed solutions.

3. Our Institutions and Organizations along with the Federal supporting Institutes and Agencies must renew a mutual commitment to support and strengthen the role of the individual Clinical and Basic Scientist. Collective and multidisciplinary efforts are necessary for many programs and initiatives, but the best of these succeed when individual prerogatives and creativity are able to flourish.

4. We uniformly support the time-proven method of evaluating and supporting Biomedical Research. We specifically endorse the budgetary requests of the respective Federal Institutes and Agencies. Any differences we may have related to the distribution, pricrity, or representation, can and should be resolved through the same mechanisms which allow for these deliberations.

STATEMENTS OF DR. THOMAS E. THOMPSON

Mr. Chairman and Members of the Committee, it is a great pleasure to be here today to testify on behalf of the National Institute of General Medical Sciences (NIGMS). As a working scientist who has benefited from the NIGMS programs, I am grateful for the opportunity to appear before you and present my views on this matter.

Over the years, this distinguished Committee has shown time and again its commitment to improving and maintaining excellence in our country's biomedical research. Just as importantly, this committee recognized the importance of insuring future generations of biomedical scientists and has actively promoted the training of students through grants and fellowships.

Mr. Chairman, it is infrequently that a scientist seeks the opportunity to testify before Congress. In these times of economic austerity, however, I feel compelled to come so that I may further impress upon you the urgency and importance of maintaining the non-categorical research programs at NIH, particularly those at the NIGMS.

Over the past thirty years, I have dedicated my scientific career to the study of biological processes at the molecular level. During this time my research and that of my colleagues has helped us better understand an extremely important part of living things: the membrane that surrounds each cell.

Not so long ago, we only knew this membrane existed; today we have come to realize the unique role it plays not only as a barrier which preserves the integrity of the cell, but also as an active participant in immune responses and general intercellular information transfer processes involving hormonal and electrical signals. Defects in the composition, structure and function of the cell membrane are the cause of many serious and widespread diseases in man including renal tubal failure, certain hemolytic anemias and cancer. Had the funding Institutes been only interested in projects which produced immediate marketable results, none of this understanding would have been possible. Had scientists not been curious about the more fundamental questions, we would still view the cell membrane as an inert bag whose only function is to hold the cell together.

It is fortunate that Congress has had the vision to fund Institutes such as NIGMS. In fact, the world leadership of our country in the biomedical areas is, in my opinion, a direct result of the continuity of funding and the maintenance of a solid research infrastructure in areas that hold promise for the future. Yes, we need applied research, particularly in medicine, but experience has shown us that this is not enough. To make the great leaps forward, we rely critically on knowledge that can only come from basic research.

In the current economic environment, there may be a tendency to view basic scientific research as a luxury, making it an easy target for those who seek quick-fix budgetary solutions. It may also be politically difficult to justify non-categorical programs, such as those supported by NIGMS, if one simply looks at the short-term return for the dollar or if immediate direct applications are expected.

A more thoughtful look at the projects that NIGMS funds, however, tells a very different story. These research grants and the students trained with Institute funds are the foundation upon which our country's scientific future in biology and medicine is built. In fact, the NIGMS is unique in this respect. There is no question in my mind that the broad charter of NIGMS and its visionary role has benefited biomedical sciences in two crucial ways: first, it has promoted research which is on the cutting edge of our scientific disciplines, and second, it has financed the training of the new generation of scientists which will continue to carry this research forward.

Mr. Chairman, I would be remiss if I did not mention the drastic reductions in funding proposed for NIGMS in 1987. The 1987 budget for NIGMS calls for a total number of new and competing grants of 689. This is 283 fewer grants that the 972 level appropriated by Congress in 1986. Even more distressing is the fact that, although prior obligations will be honored, there are no funds provided for new training grants in 1987.

As a working scientist, I am deeply disturbed by these cuts. Biomedical research has already felt the impact of the Gramm-Rudman-Hollings Law in 4.3% reductions. In my judgement, should these cuts go unchecked by Congress, we run the risk of seriously jeopardizing our scientific infrastructure.

It is not only research that is at stake, it is the demoralizing effect these cuts have on scientists. As an established investigator, the funding uncertainly limits my ability to plan and to pursue areas which, although promising, may not directly impinge on current projects.

The situation for new investigators is even worse. More and more new investigators are deterred from pursuing careers in academic research due to the pressing economic situation. This trend is already creating serious problems in the engineering field. New college graduates prefer to devote their efforts to the pursuit of more lucrative industrial careers. With fewer and fewer students seeking graduate degrees our universities are finding it harder to maintain adequate supplied of Ph.D.s to train new generations. If the same pattern develops in the biomedical field, the results could be disastrous for medicine.

I would like to request with respect that the funding level in the 1987 NIGMS budget for new and competing research grants be returned to the 1985 level of somewhat less than 1,000. I believe also that it is of critical importance that the number of trainees in the 1987 NIGMS budget be returned to the 1985 level of 3,400.

Mr. Chairman, I wish to thank you again for this opportunity to air my views. I am confident that your leadership will, as it has in the past, preserve and enhance crucial programs such as those at NIGMS.

Statements of Robert Barker, Provost, Cornell University

The National Institute of General Medical Sciences stands unique among the National Institutes of Health. It can rightfully claim to have been the vehicle for funding most of the extraordinarily important basic research that has fueled a revolution in health care and in biotechnology. Economic impacts derived from this basic research have been significant. Genetic engineering, derived from basic work on the structure of genes, is the basis for industrial application reliably projected as exceeding $100 billion within the next 20 years. Private investment has already exceeded $5 billion. Basic cell biology is the basis for the development of diagnostic and theraputic tools with a market projected to be greater than $10 billion.

In the biomedical sciences, basic discovery leads rapidly to application. Essentially all modern methods of analysis, diagnosis and therapy trace their origins to discoveries of the last thirty years and it is increasingly common for basic discoveries to have immediate implications for practice and application.

The new industries of biotechnology have arisen directly from discoveries, many of them funded by NIGMS, motivated by a desire to understand how biological systems work. In simple terms, that is the mission of NIGMS, to develop an understanding of how biological systems work. Much is known, but much more needs to be known. Present knowledge makes it clear that our greatest successes in managing biological systems, medical, commercial and agricultural, have come from basic inquiry. It should be given the highest national priority.

To concentrate funding on attempts to solve current health problems by targeted research or development based on present basic knowledge is to choose the wrong strategy. The "War on Cancer" has been effective mainly to the degree that funding was directed to basic studies. Solutions to health problems will come now only as we enlarge the science base on which effective treatment can be built. Funding to the National Institutes should be balanced. Funding of the mission-oriented institutes is vital but it should not be such as to outstrip the generation of new knowledge that is the mission of NIGMS.

Current funding levels require NIGMS to turn away outstanding proposals for research of significance to all health-oriented programs. Most of the important advances in the biomedical sciences have come from the work of individual investigators pursuing very basic questions concerning the nature of biological processes and the molecular and cellular basis for biological functions. Often, pathological conditions are important to these studies because they provide a counterpoint to the normal condition. Nevertheless, the focus is on how the biological world works and not on how to deal with a particular disease. Individual investigators funded to explore significant biological phenomena and given the freedom to seek new knowledge where it is to be found, provide information that is entirely relevant and essential to understanding and treating every human disorder. It is ironic that as the relevance of basic studies becomes more apparent, it has become more difficult to provide funding for them. I urge the Congress to sustain and even increase funding for basic research so as to ensure that future application will be founded on a solid basis of fact and understanding.

Basic research carried out in large part by NIGMS has provided the knowledge basis for the biotechnology industry. This new and important economic force in our society is derived entirely from knowledge of the molecular basis of genetics and of how to deal with complex cells in cultured systems. NIGMS can rightly claim parentage of ~~this~~ important new application of basic biology. In the last several years over two hundred new corporations have been formed. Almost every major corporation involved in the chemical or pharmaceutical industries has undertaken new initiatives. More than two thousand PhD biologists have been employed and there is a documented need for an equal number in the next several years. Much of the biotechnology industry is focused on diagnostic and theraputic methods that are more rapid and more precise than traditional methods. The impact of these strategies on medical practice is immediate and dramatic. In what might be viewed as a spinoff from NIH sponsored research, biotechnology methods are being applied in agriculture, waste management, chemical and energy production. In all cases the fundamental work of the NIGMS is properly identified as seminal to the field. The work must be given credit for the economic benefits that are now so clearly apparent. And that work should be continued and even expanded to ensure our leadership in biotechnology.

I urge that the highest national priority be given to enhancing the funding available for advanced training in the biomedical sciences.

The number of trainees supported by NIGMS has declined steadily in the last several years. It is clear now that by 1995 the demand for PhD scientists in the area will greatly exceed supply. At present, supply and demand are more-or-less in balance but enrollments of graduate students have declined by 25% in the last five or six years and the production of PhD scientists must follow that trend. Within the next several years, attrition due to retirement and other causes will increase several fold. In the mid-1990s, the supply and demand lines will cross and universities and industries alike will be unable to sustain their research and training programs in fields of critical importance to our nation's economic competitiveness.

The young scientists of 1995 are entering college now. They will make career decisions in the next two years. Failure to provide incentives to follow careers that are nationally important but that have negative economic consequences for those who select them is strongly influenced by the availability of fellowships. Fellowships reflect a national statement of priority and significance. The steady decrease in the availibility of fellowships in the basic biomedical sciences has delivered a very strong message of a declining national priority for research in that area.

Finally, I urge that stable levels of funding be provided. When funding levels fluctuate, important programs are dismantled, not on the basis of a rational decision, but on the basis of the caprice of circumstances. In addition, programs of lower priority can be funded because of the time at which they are reviewed while programs of higher priority go unfunded if they are reviewed during the lean years.

The successes of the National Institute of General Medical Sciences during the last two decades have proven conclusively that basic research pays off and that it has substantial economic value, even in the relatively short term. Funding for basic research and training in NIGMS should be given the highest priority. In my view, it has the greatest potential for benefit both in terms of improved health care and in terms of economic outcomes. Relative to other research it is inexpensive and returns value well beyond its cost.

In conclusion, I urge that funding be provided that is adequate to support 1000 new and renewal investigator initiated research grants and that at least 3400 trainees be supported with a budget of $65.5 million to cover tuitions, stipends and associated training costs.

STATEMENT OF ELVA BUSH, CERTIFIED REGISTERED NURSE ANESTHETIST, BOARD OF DIRECTORS OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS AND NURSES COALITION FOR LEGISLATION

Senator INOUYE. Our next witness is Elva Bush for the American Association of Nurse Anesthetists [AANA] and Nurses Coalition for Legislation. Good morning. Please proceed.

Ms. BUSH. Good morning. I am Elva S. Bush, and I am on the Board of Directors of the American Association of Nurse Anesthetists. I am a certified registered nurse anesthetist or CRNA, and I practice in Connecticut.

I am here today on National Nurses Day to present testimony on behalf of the AANA, the Pediatric Nurse Practitioner Group, and the Nurses Coalition for Legislation in regard to appropriations for nursing education and research.

The manpower data found in the written testimony which I am submitting today and the Institute of Medicine report on nursing and nursing education documents the importance of continued Federal assistance for nurse training and specifically CRNA-related training.

CRNA's provide a major portion of the anesthesia services in this country. For the protection of the public, CRNA's must complete a continuous and rigorous program of study with certification in the specialty of anesthesia. The cost of this education is escalating for several reasons.

First of all, hospitals cannot or will not support the educational endeavor to the extent that they have in the past. These increasing costs to hospitals and academic centers have been cited as the major reason for program closures over the past decade, from 213 programs to 106, or 50 percent. Fifty of our programs have closed in the last 3 years alone.

This country is facing the extinction of the most cost-effective anesthesia provider, when data supports a need for CRNA's. Right now there are many openings for CRNA's across the country, and over 70 institutions are advertising for one or more CRNA's in our current journal. There is a need.

Second, many of the existing programs are moving into academic settings in order to grant undergraduate and graduate degrees, making education more costly.

And third, as a part of this process, the programs are increasing in length from 24 months to 36 months.

These reasons impact directly on the students' ability to pay for their education. They must have help. The nature of the programs do not lend themselves to part-time study with outside work because of the heavy hour commitment. Some of the students do receive stipend support and tuition assistance; however, this amount pales when compared to the substantial support received by residents in training. These two groups of students are quite similar. They are approximately the same age group, 25 to 35; many of them have family obligations; and they perform quite similar functions during their education.

Appropriations to the Nurse Anesthetist Training Program is also important because of faculty development. It could allow faculty to acquire needed higher degrees and knowledge in the current methods of teaching and research.

At the present time, most of the programs funded under the Nurse Training Act do not apply to nurse anesthesia programs, which makes the Nurse Anesthetist Training Program essential. Without Federal funding support to these programs, we will be unable to meet the needs of the public.

Senator Inouye, we are recommending that Congress fund section 831 at $800,000 for fiscal year 1987. This is the same level appropriated originally in fiscal year 1986, and it is a restoration of the Gramm-Rudman cuts of 4.3 percent. It is the full amount authorized for fiscal year 1987.

Also support for advanced training and especially training in nursing in general is badly needed. The Institute of Medicine study estimated a need for twice the number of nurse specialists by 1990 than we will have. This includes administrators, teachers, nurse practitioners, nurse midwives, and nurse anesthetists.

We urge funding at the full authorization for all nurse training programs, which is $55 million. The President's budget calls for zero. In addition, the budget calls for the elimination of Medicare financing for all hospital-based education of nurses and other nonphysician providers. Medicare currently pays a proportionate share of the direct cost of education in hospitals.

The administration's proposal would continue funding by Medicare for physician training, the more expensive provider. The American Medical Association, the American Hospital Association, the American Nurses Association, and our coalition oppose this proposal.

And finally, we urge funding at the level of $18.5 million for the Center for Nursing Research programs, which is $2 million more than fiscal year 1986. This would enable expansion of research training by $1 million and research grant support by $1 million.

The Institute of Medicine report showed a growing need for research training support in nursing. Applications for research fellowships have increased significantly. The Institute of Medicine recommends expanded training levels by about 100 percent by 1990.

Like other newly developing fields of research, nursing should receive sufficient support for research grants to generate major interest in the nursing community in research. Ultimately this research will benefit the public.

Of particular importance is research dealing with the qualitative aspects of nursing services and their cost effectiveness. We believe Congress and the public must be informed as to the value of nursing services of many types which are alternatives to the more costly existing services. Such models include expanded use of nurse specialists in many areas of service, including anesthesia.

It seems appropriate that I should come before you today on this day of celebration for all nurses to request Congress' continued support for nursing education and research, and I thank you for this opportunity.

Senator INOUYE. I'm certain that this subcommittee will be most favorably inclined.

Ms. BUSH. I'm delighted to hear that. Thank you.

PREPARED STATEMENT

Senator INOUYE. Thank you very much.

[The statement follows:]

STATEMENT OF ELVA BUSH

My name is Elva Bush and I am on the Board of Directors of the American Association of Nurse Anesthetists. I am a certified registered nurse anesthetist (C.R.N.A.) and practice in Connecticut.

1. Background re: CRNA Practice

CRNA' are highly educated, licensed health professionals who have been providing a major portion of the anesthesia services in this country for about 100 years. There are more than 20,000 active practicing CRNA's providing 70 percent of the anesthesia care in rural areas and 50 percent of such services across the nation. Their practice is legally sanctioned through State laws and regulations in all 50 states and U.S. territories.

This is a profession with rigorous standards. The basic curriculum of an accredited nurse anesthesia educational program in the United States requires a minimum of twenty-four months of study and is offered at baccalaureate and masters degree levels or as a certificate-granting program. Licensed professional nurses entering these programs must have a minimum of one year of nursing experience in an acute care setting. However, the typical application has at least two years of nursing experience in an intensive care unit.

2. Justification for Continued Support

The need for continued support for nurse anesthesia education can be justified for a variety of reasons. These follow.

a. Federal Studies regarding supply and demand.

The demand for nurse anesthesia services has been demonstrated in a variety of studies. According to a 1977 HEW study, the projected need for CRNA' ranged between 22,267 and 25,530 for 1980. Currently there are 20,000 active practicing CRNA' and this products a shortfall of from 3,312 to 6,000 compared to what was needed in 1980. With the disturbing drop in the number of nurse anesthesia education programs, we are producing a net increase of less than 500 CRNA's per year (approximately 1000 new graduates are produced each year). Since our specialty is some ninety years old, our attrition from the ranks of active practice approximates 700 per year - from retirement, death, disability or other causes.

The increasing age of the American public will also contribute to an increased demand for anesthesia providers in the coming years. The Census Bureau projects that elderly Americans will double in number between the years 1980 and 2020, and that by the year 2030 one in every five people will be at last 65 years old. The average life expectancy for those people born in 1982 is 74.5 years, according to the National Center for Health Statistics. This type of information points to an increased need for CRNA' in the future. As the average life expectancy increases, the percentage of the elderly population will also increase. It can be expected that this will result in an increase in numbers of surgical procedures as well as their complexity.

The Institute of Medicine - National Academy of Science report entitled "Nursing and Nursing Education" recommended: "The federal government should expand its support of fellowships, loans, and programs at the graduate level to assist in increasing the rate of growth in the number of nurses with master's and doctoral degrees in nursing and relevant disciplines. More such nurses are needed to fill positions in administration and management of clinical services and of health care institutions, in academic nursing (teaching, research, and practice)," Nurse anesthetists were one of the groups specifically addressed in this report.

3. Cost of Nurse Anesthesia Education

The cost of nurse anesthesia education is escalating because of a variety of reasons: (1) the inability of hospitals to fiscally support this educational endeavor to the extent it has in the past; (2) the movement of these educational programs into academic settings at the graduate level; and (3) the length of programs ranging from 24-30 calendar months. The increased cost of nurse anesthesia education had been a major reason for the decrease in nurse anesthesia education programs over the past decade by one-third, i.e from 213 to 137. Prior to the mid seventies, students often received stipends and tuition assistance from hospitals. However, with the increasing cost constraints placed on hospitals, this support has all but dried up.

4. Lack of Other Available Financing Sources

The data support the need for CRNA's as cited in our written testimony. Traineeship support is important to meet the need.

The nature of nurse anesthesia education does not lend itself to part-time study and part time work because the classroom and clinical commitment requires approximately sixty four hours per week. It is essential to complete this curriculum since certification in this specialty is required for entry into practice.

Most of the programs funded under the Nurse Training Act do not apply to nurse anesthesia educational programs, making the Nurse Anesthetist Traineeship Program essential to this nursing specialty. It is essential to simply enable the current number of students to maintain their educational programs.

In addition, the program authorizes faculty training support to enable existing faculty to upgrade their academic credentials and improve their knowledge in areas such as research and educational methods related to anesthesia. Increasing the numbers of well trained teachers will assist in maintaining our current educational programs. There has been a reduction in the number of programs recently. The Institute of Medicine report specifically recommends expanding support for the training of faculty. Faculty training support and research training support are critical for the nursing profession as a whole.

Nurse Training Support for Anesthesia Traineeship

We recommend that Congress fund Section 831 at $800,000 in FY87, the same amount as in FY86 and the amount authorized by Section 831 for FY87.

Nursing Research

The Health Research Extension Act, PL99-158, created the National Center for Nursing Research within the NIH. The Center is authorized to support basic and clinical nursing research, research training and programs in patient care research. Like NIH Institutes, the Center has an Advisory Council responsible for advising the Center on grants to be supported and on policy related to nursing research. The Center is now established and has 9 staff. A Search Committee is presently reviewing applications for the position of Director of the Center.

IN FY1986 $9.4 million was appropriated for nursing research grants and another $5 million was added, independent of that amount, to assist in establishing the center and its programs. Another $2 million has been appropriated for research training related to nursing research. These funds are all administered by the Center. The President has requested no funding for these programs.

We urge funding at the level of $18.5 million in total for the Center and training programs, $2 million more than in FY86. This level of funding would enable expansion of research training by $1 million and expansion of the research grant program by $1 million. Recently an Institute of Medicine report indicated a growing need for research training support in nursing. Applications for research training fellowships increased by 50% in FY 85 and about 30% this year. The Institute of Medicine recommends doubling the number of fellowships by 1990.

Like other newly developing fields of research such as geriatrics, this field should receive sufficient support for research grants to generate major interest in research in the nursing community. Areas of research which are funded include health promotion services and preventative care, maternal and child health and assessments of cost and productivity of clinical programs. Of particular importance is research to improve the qualitative aspects of nursing services and their cost effectiveness. We believe that Congress and the public must be informed by clinical research as to the value of nursing services and the fact that their expanded utilization would be cost effective.

Nursing research is of high quality, Mr. Chairman. For example, there are currently unfunded proposals totaling about $2 million which are approved with scores higher than those NIH is generally funding; 150 or better. We need sufficient additional funds to support such high quality research.

STATEMENT OF EUGENE S. MAYER, M.D., ASSOCIATE DEAN AND AREA HEALTH EDUCATION CENTERS DIRECTOR, SCHOOL OF MEDICINE, UNIVERSITY OF NORTH CAROLINA

Senator INOUYE. Our next witness is Dr. Eugene Mayer, associate dean, School of Medicine, University of North Carolina. Dr. Mayer?

Dr. MAYER. Good morning, Mr. Chairman. It's nice to be with you again this year.

I am Dr. Eugene Mayer, associate dean of the School of Medicine at the University of North Carolina and director of the North Carolina Area Health Education Centers Program or AHEC. I am here representing 24 projects in 27 States that are receiving Federal AHEC funding.

We appreciate the support that we have received through the years from you and from the subcommittee. We believe it is essential that the AHEC Program continue and urge the Congress to continue to appropriate $18 million for fiscal year 1987.

Throughout the United States, we are continuing to attack the problem that led to the establishment of the program, that being the maldistribution of physicians and other practitioners in rural and inner city areas, and I am happy to report that we are making important progress around the country.

In my State of North Carolina, for example, during the decade before our program, only 41 percent of our counties experienced an improving ration of physicians to population. During the following decade, 89 percent of our counties found their ratios improving, and we are the fourth most rural State.

Many other States with AHEC programs, including California, New Mexico, North Dakota, South Carolina, West Virginia, are reporting similar successes. We can be proud of that, but much remains to be done. Many rural and inner city areas still do not have enough physicians, nurses, and other health professionals.

Particularly distressing is the fact that this problem persists at a time when we are hearing talk about an oversupply of physicians. I invite anyone to try discussing the idea of a doctor glut with a pregnant woman in western North Carolina who needs to travel 45 miles to receive routine prenatal care. The truth is that our young physicians still do not tend to set up practice in rural or inner city areas unless they receive a lot of special attention. The AHEC Program helps to provide that attention.

The maldistribution of health professionals in rural and inner city areas is a terribly difficult problem. That was something we recognized at the time that the AHEC concept was developed 15 years ago. We knew we were talking about a tremendous effort that would need to be measured in terms of decades, not years. The AHEC Program has evolved into an effective partnership involving Federal, State, and local governments, health science schools, community hospitals, and health practitioners. The partnership involves the other primary care initiatives of the Federal Government as well.

That kind of cooperation seems to happen all too rarely in our society. We have many types of people from the public and private sector working together. For example, in North Carolina, over 25 percent of our State's private practitioners regularly teach students and residents in this program. AHEC programs enable students and medical residents to take a portion of their clinical training at community hospitals and health centers. The students and the residents receive an exposure to practicing physicians in a community setting. The local agencies get the services of highly qualified health personnel, and the people of the community have access to better health care.

The hope is that some of the young health professionals will decide to practice in rural or inner city areas. In North Carolina, 70 percent of the family practice residents trained in AHEC settings have remained in the State, and 50 percent of these have located in towns of fewer than 5,000 persons.

The AHEC Program also works with health science schools to offer continuing education to practicing health professionals. This service not only helps community practitioners feel less isolated, but also assures them that they can keep up to date even if they practice far from the major medical centers.

I am happy to report that AHEC's around the Nation are grassroots organizations that have been successful in adapting programming to meet changing needs within interdisciplinary programs developing in aging, health promotion, disease prevention, cost containment, and mental health.

Mr. Chairman, the National AHEC Program has proven to be a wise investment. Since 1972, Federal funding for AHEC has totaled about the same amount that the United States obligates for the Health Care Financing Administration every 2 to 3 days. That modest amount of funding has led to the establishment of AHEC's for 32 States, and it has spurred State governments into spending hundreds of millions of dollars for AHEC programs. This year, for example, the State of North Carolina has appropriated $26 million for AHEC activities.

The National AHEC Program demonstrates our Government working at its best, and we invite the subcommittee to review the strong endorsements contained in several national studies.

We hope that in the fiscal year 1987 budget the Congress will maintain its commitment to a program aimed at ending the maldistribution of physicians and health practitioners in rural and inner city areas. The United States, Mr. Chairman, we believe cannot afford to be without this program.

PREPARED STATEMENT

Thank you again for the opportunity to appear before you today.

[The statement follows:]

STATEMENT OF EUGENE S. MAYER

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, I AM DR. EUGENE MAYER, AND I AM ASSOCIATE DEAN OF THE SCHOOL OF MEDICINE OF THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL AND DIRECTOR OF THE NORTH CAROLINA AREA HEALTH EDUCATION CENTERS PROGRAM, OR AHEC, AS WE CALL IT. I AM HERE TODAY ON BEHALF OF 24 AHEC PROJECTS IN 27 STATES THAT ARE RECEIVING FEDERAL AHEC FUNDING THROUGH THE HEALTH RESOURCES AND SERVICES ADMINISTRATION. AND I AM HERE ON BEHALF OF THE MILLIONS OF AMERICANS WHO HAVE BENEFITTED OR STAND TO BENEFIT FROM THIS IMPORTANT NATIONAL PROGRAM FOR IMPROVING HEALTH CARE.

WE AT AHEC APPRECIATE THE SUPPORT THAT WE HAVE RECEIVED THROUGH THE YEARS FROM YOU, FROM THIS SUBCOMMITTEE AND FROM THE CONGRESS AS A WHOLE. WE BELIEVE IT IS ESSENTIAL THAT THE NATIONAL AHEC PROGRAM CONTINUE. WE URGE THE CONGRESS TO CONTINUE TO APPROPRIATE $18 MILLION FOR FISCAL YEAR 1987 FOR THIS PROGRAM, WHICH IS CURRENTLY AUTHORIZED UNDER TITLE VII, SECTION 781 OF THE PUBLIC HEALTH SERVICE ACT.

THROUGHOUT THE UNITED STATES WE ARE CONTINUING TO ATTACK THE PROBLEM THAT LED TO THE ESTABLISHMENT OF THE NATIONAL AHEC PROGRAM -- THAT PROBLEM BEING THE MALDISTRIBUTION OF PHYSICIANS AND OTHER HEALTH PRACTITIONERS IN RURAL AND INNER CITY AREAS. I AM HAPPY TO REPORT, MR. CHAIRMAN, THAT WE IN AHEC ARE MAKING IMPORTANT PROGRESS AROUND THE COUNTRY.

IN MY HOME STATE OF NORTH CAROLINA, FOR EXAMPLE, DURING THE DECADE BEFORE OUR AHEC PROGRAM WAS ESTABLISHED, ONLY 41 PERCENT OF OUR COUNTIES HAD EXPERIENCED AN IMPROVING RATIO OF PHYSICIANS TO POPULATION. BUT DURING THE FOLLOWING DECADE, 89 PERCENT OF OUR COUNTIES FOUND THEIR PHYSICIAN-TO-POPULATION RATIOS IMPROVING.

HERE IS ANOTHER COMPARISON: WHEN THE AHEC PROGRAM BEGAN IN NORTH CAROLINA IN 1972, NON-METROPOLITAN COUNTIES IN OUR STATE HAD AN AVERAGE OF FIVE PHYSICIANS PER 10,000 POPULATION. NOW, THERE ARE SEVEN PHYSICIANS PER 10,000 POPULATION.

MANY OTHER STATES WITH AHEC PROGRAMS -- INCLUDING CALIFORNIA, NEW MEXICO, NORTH DAKOTA, SOUTH CAROLINA AND WEST VIRGINIA -- ARE REPORTING SIMILAR SUCCESSES IN BROADENING THE GEOGRAPHIC DISTRIBUTION OF HEALTH PROFESSIONALS. MANY AMERICANS NOW ENJOY A STANDARD OF

HEALTH CARE THAT WOULD HAVE SEEMED UNIMAGINABLE TO THEM TWO DECADES AGO. WE ALL CAN BE PROUD OF THAT. BUT MUCH REMAINS TO BE DONE.

MANY RURAL AND INNER CITY AREAS AROUND THE UNITED STATES STILL DO NOT HAVE ENOUGH PHYSICIANS, NURSES AND OTHER HEALTH PROFESSIONALS. MILLIONS OF PERSONS ARE AFFECTED -- FROM THE NEWBORN TO THE ELDERLY. GENERATIONS OF FAMILIES HAVE LIVED, SUFFERED AND DIED WITHOUT ACCESS TO PROPER HEALTH CARE. IT IS A TRAGEDY.

PARTICULARLY DISTRESSING IS THE FACT THAT THIS PROBLEM PERSISTS AT A TIME WHEN WE ARE HEARING A LOT OF TALK ABOUT A POTENTIAL OVERSUPPLY OF PHYSICIANS IN GENERAL. **I INVITE ANYONE TO TRY DISCUSSING THE IDEA OF A DOCTOR GLUT WITH A PREGNANT WOMAN IN WESTERN NORTH CAROLINA WHO NEEDS TO TRAVEL 45 MILES TO RECEIVE ROUTINE PRE-NATAL CARE.**

THE SIMPLE TRUTH IS THAT YOUNG PHYSICIANS DO NOT TEND TO SET UP PRACTICE IN RURAL OR INNER CITY AREAS UNLESS THEY RECEIVE A LOT OF SPECIAL ATTENTION. **AHEC PROVIDES THAT ATTENTION.**

THE MALDISTRIBUTION OF HEALTH PROFESSIONALS IN RURAL AND INNER CITY AREAS IS A TERRIBLY DIFFICULT PROBLEM, MR. CHAIRMAN. THAT WAS SOMETHING THAT WE IN THE MEDICAL COMMUNITY RECOGNIZED AT THE TIME THE AHEC CONCEPT WAS BEING DEVELOPED 15 YEARS AGO. THE CONGRESS RECOGNIZED IT, TOO, AND PASSED LEGISLATION THAT PROVIDED FEDERAL FUNDS FOR THE NATIONAL AHEC PROGRAM. EVERYONE INVOLVED KNEW WE WERE TALKING ABOUT A TREMENDOUS EFFORT THAT WOULD NEED TO BE MEASURED IN TERMS OF DECADES, NOT YEARS.

THE AHEC PROGRAM HAS EVOLVED INTO AN EFFECTIVE PARTNERSHIP INVOLVING THE FEDERAL GOVERNMENT, STATE GOVERNMENTS, LOCAL GOVERNMENTS, HEALTH SCIENCE SCHOOLS, COMMUNITY HOSPITALS AND HEALTH PRACTITIONERS. THE PARTNERSHIP INVOLVES THE OTHER PRIMARY CARE INITIATIVES OF THE FEDERAL GOVERNMENT, AS WELL. THAT KIND OF COOPERATION SEEMS TO HAPPEN ALL TOO RARELY IN OUR SOCIETY, AND WE WHO ARE ASSOCIATED WITH AHEC FEEL MOST FORTUNATE. WE HAVE ALL TYPES OF PEOPLE FROM THE PUBLIC AND PRIVATE SECTORS WORKING TOGETHER IN PURSUIT OF A COMMON PUBLIC POLICY OBJECTIVE. FOR EXAMPLE, IN NORTH CAROLINA, OVER 25 PERCENT OF OUR STATE'S PRIVATE PHYSICIANS REGULARLY TEACH THROUGH THIS PROGRAM.

THE AHEC PROGRAMS ENABLE STUDENTS AND MEDICAL RESIDENTS AT HEALTH SCIENCE SCHOOLS TO TAKE A PORTION OF THEIR CLINICAL TRAINING AT COMMUNITY HOSPITALS AND HEALTH CENTERS -- AN ARRANGEMENT THAT ENDS UP BENEFITTING EVERYONE. THE STUDENTS AND THE RESIDENTS RECEIVE AN EXPOSURE TO PRACTICING PHYSICIANS IN A COMMUNITY SETTING -- SOMETHING THEY MIGHT NOT HAVE HAD OTHERWISE. THE LOCAL AGENCIES GET THE SERVICES OF HIGHLY QUALIFIED HEALTH PERSONNEL. AND THE PEOPLE OF THE COMMUNITY HAVE ACCESS TO BETTER HEALTH CARE.

THE HOPE, OF COURSE, IS THAT SOME OF THE YOUNG HEALTH PROFESSIONALS WHO PARTICIPATE IN THIS COMMUNITY-BASED PROGRAM WILL DECIDE AFTER COMPLETING THEIR EDUCATION TO PRACTICE IN RURAL OR INNER CITY AREAS -- THE AREAS WHERE HELP IS DESPERATELY NEEDED. **IN NORTH CAROLINA, 70 PERCENT OF THE FAMILY PRACTICE RESIDENTS TRAINED IN AHEC HAVE REMAINED IN THE STATE, AND 50 PERCENT OF THOSE HAVE LOCATED IN TOWNS OF FEWER THAN 5,000 PERSONS.**

THE AHEC PROGRAMS ALSO WORK WITH HEALTH SCIENCE SCHOOLS TO OFFER CONTINUING EDUCATION AND TECHNICAL ASSISTANCE TO PRACTICING HEALTH PROFESSIONALS THROUGHOUT A STATE. THIS SERVICE NOT ONLY HELPS COMMUNITY-BASED PROFESSIONALS FEEL LESS ISOLATED BUT ALSO ASSURES THEM THAT THEY CAN KEEP UP TO DATE EVEN IF THEY PRACTICE FAR FROM THE MAJOR MEDICAL CENTERS.

I AM HAPPY TO REPORT ALSO THAT AHECS AROUND THE NATION HAVE BEEN SUCCESSFUL IN ADAPTING PROGRAMMING TO MEET CHANGING COMMUNITY NEEDS. MAJOR EFFORTS HAVE BEEN UNDERTAKEN TO DEVELOP INTERDISCIPLINARY EDUCATIONAL PROGRAMS IN COMMUNITY SETTINGS IN THE AREAS OF AGING, HEALTH PROMOTION, DISEASE PREVENTION, HEALTH SERVICES MANAGEMENT, COST CONTAINMENT, AND MENTAL HEALTH.

MR. CHAIRMAN, THE NATIONAL AHEC PROGRAM HAS PROVEN TO HAVE BEEN A WISE INVESTMENT FOR THE FEDERAL GOVERNMENT. SINCE 1972, FEDERAL FUNDING FOR AHECS NATIONWIDE HAS TOTALED ABOUT THE SAME AMOUNT THAT THE U.S. OBLIGATES FOR THE HEALTH CARE FINANCING ADMINISTRATION EVERY TWO TO THREE DAYS. THAT MODEST AMOUNT OF FEDERAL SPENDING HAS LED TO THE ESTABLISHMENT OF AHECS FOR 32 STATES, 27 OF WHICH ARE STILL RECEIVING FEDERAL FUNDS, AND IT HAS SPURRED STATE AND LOCAL GOVERNMENTS INTO SPENDING HUNDREDS OF

MILLIONS OF DOLLARS FOR AHEC PROGRAMS. THIS YEAR, FOR EXAMPLE, THE STATE OF NORTH CAROLINA HAS APPROPRIATED $26 MILLION FOR AHEC ACTIVITIES.

THE NATIONAL AHEC PROGRAM DEMONSTRATES OUR GOVERNMENT WORKING AT ITS BEST. WE INVITE THE SUBCOMMITTEE TO REVIEW THE STRONG ENDORSEMENTS OF THE AHEC PROGRAM CONTAINED IN THE FOLLOWING STUDIES:

1. THE 1978 REPORT OF THE GENERAL ACCOUNTING OFFICE;
2. THE 1978 REPORT OF THE SURVEY AND INVESTIGATIONS STAFF OF THE HOUSE APPROPRIATIONS COMMITTEE;
3. THE 1976 AND 1979 REPORTS OF THE CARNEGIE COUNCIL;
4. THE 1980 REPORT TO THE CONGRESS BY THE SECRETARY OF HEALTH, EDUCATION AND WELFARE; AND
5. THE 1980 REPORT OF THE GRADUATE MEDICAL EDUCATION NATIONAL ADVISORY COMMITTEE, CALLED THE GMENAC REPORT.

WE AT AHEC HOPE THAT IN THE FISCAL YEAR 1987 BUDGET THE CONGRESS WILL MAINTAIN ITS COMMITMENT TO A PROGRAM AIMED AT ENDING THE MALDISTRIBUTION OF PHYSICIANS AND HEALTH PRACTITIONERS IN RURAL AND INNER CITY AREAS. THIS COMMITMENT ALLOWS FOR FUNDING OF STATEWIDE AHECS, REGIONAL AHECS, AND AHEC SPECIAL INITIATIVES. THE UNITED STATES, MR. CHAIRMAN, CANNOT AFFORD TO BE WITHOUT THIS PROGRAM.

THANK YOU AGAIN FOR THE OPPORTUNITY TO APPEAR HERE TODAY. WE IN THE AHEC PROGRAM LOOK FORWARD TO CONTINUING TO WORK WITH THE CONGRESS IN THE INTEREST OF ENSURING ACCESS TO PROPER HEALTH CARE FOR ALL AMERICANS.

Senator INOUYE. Dr. Mayer, according to your study, what are the major causes of this maldistribution?

Dr. MAYER. It's very complicated, Senator. But like most people, young physicians have the lure of the city and residential and suburban areas, and it's very hard to get people to go where there aren't adequate shopping centers or public schools for the family, this sort of thing.

There is a group of professionals, however, that research has shown is really much more interested in professional stimulation than they are in social stimulation. It's that group of people that we hope—that we try to pitch this program to. We believe that if we can produce and provide educational stimulation by the presence of students, residents, educational programs, continuing education, that the practitioner who chooses to settle in a rural area will at least be less isolated professionally and more stimulated and possibly, then, more likely to stay there for practice and stay up to date.

Senator INOUYE. Does tort liability play any part?

Dr. MAYER. Tort liability does play a part. And what we're seeing unfortunately in our State is where we have made, as I said in my testimony, where we have seen 50 percent—about 80 percent of our residents in family medicine stay in the State with one-half of those staying in towns of 5,000 or less, many of those being family practitioners, and particularly many of those who deliver babies, we are seeing the tort issues in our State and the skyrocketing liability premiums come to the point where we now have—we have lost something like 85 percent in the last year of our family practitioners who deliver babies. They are no longer delivering, and many of them are literally leaving the small towns, because without that aspect of their practice, it hurts their economic base as well.

Senator INOUYE. How will AHEC try to assist in this area?

Dr. MAYER. In the direct sense, we don't deal with the tort reform issue. That's sort of a separate issue in our State. However, on a very personal basis, I happen to be very involved with our general assembly's efforts with respect to tort reform through my responsibilities in the North Carolina Medical Society and through various committees that I sit on in behalf of the State government. And so in that sense, we are trying to influence tort reform. The nine regional centers that we call AHEC in North Carolina are all very active politically with county commissioners, with hospital boards of trustees, working in a coordinated way toward tort reform, and we think we're going to see some progress next month.

Senator INOUYE. I thank you very much, doctor.

Dr. MAYER. Thank you, sir.

STATEMENT OF RASHI FEIN, CONSORTIUM OF SOCIAL SCIENCE ASSOCIATIONS, PROFESSOR OF ECONOMICS, HARVARD MEDICAL SCHOOL

Senator INOUYE. Our next witness is professor of economics at Harvard Medical School, Dr. Rashi Fein. Am I pronouncing your name correctly?

Mr. FEIN. That's correct, Senator.

Mr. FEIN. Good morning. My name is Rashi Fein. I am professor of the economics of medicine at the Harvard Medical School. Prior to that, I was at the Brookings Institution and on the staff of the Council of Economic Advisors and the University of North Carolina at Chapel Hill.

I am pleased to have this opportunity to appear before you on behalf of the Consortium of Social Science Associations to testify on the need for support for social science research on health care services, organization, finance, and related topics.

In the 35 years since I entered the field of health economics, there has been a revolution in the size and scope of the health sector. The friendly doctor with the black bag making a house call has given way to for-profit and not-for-profit hospitals, tax-exempt bonds, third-party payments, premiums, reimbursements, benefit packages, health maintenance organizations, specialists, tests, technology, machinery, research, laboratories, and ever-rising costs.

Our grandparents' financial and physical well-being, as related to medical care, did not depend on the views of Presidents, Members of congressional committees, State legislators, or corporate executives. Today they do.

These and other changes have favorable and unfavorable effects requiring study and analysis that uses the tools of modern applied social science. Yet aware of the severe constraints on Federal expenditures, both you and I must ask, why does study and analysis require Federal support?

I believe that the Federal Government has a stake in the applied research and data-gathering efforts deriving from the need to promote the general welfare and, within that, the health of the citizenry. I know that there are individuals who believe that national and individual welfare is best advanced by free and competitive markets. Nevertheless, we are a very long way from the situation in which knowledgeable and sovereign consumers face competitive markets characterized by ease of entry and competition. There, therefore, is the need to understand how the health sector is evolving and with what effects on dollar costs, the distribution of care, and importantly quality.

These matters are also of concern to the Federal Government because it is spending over $100 billion a year on personal health care, research, and construction. Government needs to know more about what it is getting for those dollars and whether it can get better value for its money.

I am not here to sketch a detailed applied research agenda, but I would take note of a few issues.

First, much of the research needs to be done outside of Government. There are three reasons for the support of extramural research.

First, Government's actions—DRG's, for example—affect the whole field of health care. It simply is inappropriate for us to rely exclusively on Government to evaluate the consequences of its own actions.

Second, Government these days is preoccupied with dollars and cost containment efforts. Vital as these are, the agenda for health services research includes quality, variations in practice patterns, the impact of different delivery modalities, and different payment and insurance patterns. Much of the analytical effort falls in the domain of the social sciences.

Third, applied research carried on outside of Government enables students and junior researchers to gain experience. We need to support research endeavors of national research service awards that help educate future researchers.

Nevertheless, I must stress the importance of adequate funding of intramural efforts. I do so for two reasons.

The first is based on the general proposition that extramural research is enhanced by an in-house research capability. Different relationships are built between grantor and grantee, resulting in better and more useful research and in an increase in Government's ability to apply the results of that research.

The second reason can be illustrated by noting the paucity of data available on such important issues as the distribution of health expenditures and insurance and the factors associated with that distribution, the kind of data that can be gathered by an adequately funded national medical expenditure survey. It is shocking that in 1986 we are still forced to rely on data for 1977, the time of the last survey. My prepared testimony discusses this more fully.

I would also note that in the last few years we have learned that both the dollar costs and quality of medical care varies tremendously across our country and often in small areas contiguous to each other. Practice patterns are different, but why? With what implications? What can be done about them?

Funding for social science research in that arena may help bring us the best of all worlds, more effective care at lower cost.

Finally, though I have mentioned the National Centers for Health Services Research, I want to particularly note the importance of encouraging the NIH agencies in sponsoring this type of work and in particular the National Institute on Child Health and Human Development [NICHD] and the National Institute on Aging, which are focused on particular population groups.

PREPARED STATEMENT

I would conclude by saying that we cannot guarantee that every question that an applied researcher might ask is worth asking or that every answer obtained has implications for public policy. But we can guarantee that if we don't obtain the data and if we don't ask the questions and if we don't train the researchers and if we don't seek answers, we will continue to waste health care dollars, and we will run risks of creating a health care system in which quality is sure to suffer and access is sure to decline.

Thank you.

[The statement follows:]

STATEMENT OF RASHI FEIN

Good Morning. My name is Rashi Fein. I have been Professor of the Economics of Medicine at the Harvard Medical School since 1968. Prior to that I was at the Brookings Institution, the staff of the Council of Economic Advisers, and the University of North Carolina at Chapel Hill. I received my Ph.D. in Economics from The Johns Hopkins University. I am pleased to have this opportunity to appear before you on behalf of the Consortium of Social Science Associations and to testify on the need for support for social science research on health care services, organization, finance, and related topics. COSSA represents more than 185,000 American scientists across the full range of the social and behavioral science disciplines, serving as a bridge between the academic research community and the Washington community. [A list of COSSA Members, Affiliates and Contributors is attached.]

When I entered the field 35 years ago there was very little social science research on health care services and there were only a few professionally trained health economists. Perhaps this is explained by the fact that the health care industry was much smaller and its organization was much simpler. Health care expenditures represented only 4.5 percent of the Gross National Product, health insurance had not yet spread throughout the land, two-thirds of personal health care expenditures were out-of-pocket, the federal government was spending less on health care than state and local governments were, and so forth.

In these 35 years there has been a revolution in the size and scope of the health sector, a sector that touches every American and that provides services that sooner or later all of us seek. The friendly doctor with a black bag making a house call has given way to for-profit and not-for-profit hospitals, tax-exempt bonds, third-party payments, premiums, reimbursements, benefit packages, health maintenance organizations, specialists, tests, technology, machinery, research, laboratories, and ever-rising cost. Our grandparents' financial or physical well-being, as they related to medical care, did not depend on the views of presidents, members of congressional committees, state legislators, or corporate executives. Today they do.

Health care is a $400 billion industry that absorbs over 10 percent of the nation's product, that strains budgets in the public sector, reduces wages and profit in the private sector, puts us in a less favorable competitive position in international trade — all this, by the way, while not providing access to millions of Americans. Health care is too large and too important to be left to America's physicians, hospitals or insurance companies.

Perhaps the dimension of change is illustrated by reminding ourselves that a dozen terms now part of the vocabulary didn't exist just a few years ago: HMO, PPO, DRG, Propac, Managed Care, are only a few examples.

These and other changes are important and their favorable and unfavorable effects require study and analysis. Much of the analysis requires the tools of modern applied social science. It takes people and money. Yet, excruciatingly aware of the severe constraints on federal expenditures, both you and I must ask: Why does study and analysis require federal support? Are health services researchers simply engaged in a knee-jerk, reflex action when they turn to Washington? What would happen if, pressed by competing demands, the Congress turned aside?

I believe the federal government has a responsibility and a stake in the applied research and data gathering efforts that I refer to. That responsibility derives from the need to promote the public welfare and within that the health of the citizenry.

I know that there are individuals who believe that national and individual welfare is best advanced and protected by free and competitive markets and that that government is best that governs least. Yet they themselves would recognize that the health care industry is not a model of competitive behavior. They would surely agree that even if the forces of competition are gathering strength, there is a need to make certain that those forces -- impelled by new methods of paying for care and, often, by a quest for profits -- not impinge unfavorably on the quality of care.

We are a very long way, and in my judgment will remain that way, from a situation in which knowledgeable and sovereign consumers face a competitive market characterized by ease of entry and competition. Even for those who believe in competition, there is the need to understand far better than we do, how it is evolving and with what effects on the distribution of care, on quality, and on dollar costs.

Futhermore these matters are of concern to the federal government not only because the health of the people and of the health sector are its concern, but also because it is spending over $100 billion a year on personal health care, research, and construction. Social science research on health care services is an investment. Viewed in the narrowest sense, if government is spending over $100 billion it ought to know more about what it and the American people are getting for those dollars and whether we can get better value for money.

I am not here to sketch a detailed applied research agenda. But I do believe it is appropriate to take note of a few issues. First, much — not all, but much — of the research needs to be done outside government. While I have a high regard for the capability of individuals and the collective expertise in various government agencies we nonetheless need to support work outside of government.

There are three reasons for the support of extra-mural research. One, government is a big player, whose actions (DRG's for example) affect the whole field of health care. It simply is inappropriate for us to rely exclusively on government to evaluate the consequences of its own actions. In this, as in other areas, we need the whistle blowers. Two, government is preoccupied with dollars and cost-containment efforts. Vital as these are, the agenda for health care services must be broader. It includes quality, variations in practice patterns, the impact of different delivery modalities and of different payment and insurance patterns. While these affect dollar expenditures, much of the analytical effort falls in the domain of the social sciences, requires skills other than economics, and techniques that do not focus on expenditures alone. Three, it is in applied research carried on outside of government that students and junior researchers get the experience that will provide us with our future strength. If we want more than technicians, if we want people who understand the nuances of the health care system and of the data it generates, we need to support research endeavors that help educate future researchers by introducing them to important ongoing research projects.

Even so, I must stress the importance of adequate funding of intra-mural efforts. I do so for two reasons. The first is based on the general proposition that effective administration of extra-mural research is enhanced by an in-house research capability. Different relationships are built between grantor and grantee resulting in better and more useful and pointed research and in an increase in government's ability to apply the results of the research. Government should not be a mere conduit for money.

The second reason is of equal, some would argue of even greater, importance. Let me illustrate the problem by noting the paucity of data available on such important issues as the distribution of health expenditures and insurance and the factors associated with that distribution, the kind of data that can be gathered by an adequately funded National Medical Expenditure Survey. In 1986 we are forced to rely on data from 1977 — and this in a field that is changing. National data cannot be gathered by individual researchers with foundation or federal grants. Only adequately supported efforts at the national level — channeled through organization such as the National Center for Health Services Research — will suffice. NCHSR is a treasure. It has been built over a period of years. Its effectiveness and utility can be enhanced by providing the resources to gather and to analyze the data that you and the private sector need to make wise policy decisions.

I should also note that in the last few years we have learned that both the dollar cost and quality of medical care vary tremendously across our country — and often in small areas contiguous to each other. Practice patterns are different. But why? With what implications? What can be done about them? Funding for social science research in that arena is necessary and, I believe, can help bring us the best of all worlds: more effective care at lower cost.

Finally, I note that though I have specifically mentioned NCHSR, I do not want, by omission, to imply that other agencies have no role to play in social science on medical care. Indeed, that is not the case. I specifically note the importance of encouraging the NIH agencies in sponsoring such work. In particular the NICHD and the NIA, focussed as they are on the needs and problems of particular segments of society rather than on particular diseases, need the funds to sponsor work that cuts across the various social science disciplines. Some of that work could involve collaboration with NCHSR, or other operating agencies within the Department of Health and Human Services. For example, the utility of the National Medical Expenditure Survey could be enhanced if NIA could buy into that survey and by adding dollars at the margin make certain that the survey generates enough information about the needs of the elderly.

Let me summarize:

(1) The health sector is changing rapidly. We need to have more baseline data and more analysis to better assess the implication of those changes.

(2) The federal government should support such analysis. Its stake is large and will continue to be large in no small part because of the size of its expenditures for health care and its valid concern for the quality of health care services.

(3) There is no substitute for federal dollars. Small as the health care research budget is in the federal scheme of things, it is too large to be substituted for by private foundations. Furthermore, the foundations are making maximal effort in the experimentation and demonstration arena — as government cuts back its own support and appears to be more timid about entering areas that require innovative experiments and new delivery systems.

(4) Social science research needs both extra- and intra-mural effort. The one cannot substitute for the other. The Congress should support adequate funding of the National Medical Expenditure Survey and such support should not come at the expense of NCHSR's extra-mural research activities.

(5) The research menu and the loci of activities are many. Within that richness, there should be room for work on small area practice variations, and support for social science research in the NIH agencies.

(6) None of us can guarantee that every question that applied research might ask is worth asking or that every answer obtained has implications for public policy — as you cannot guarantee that Congress would act appropriately on every health policy issue it addresses. But I believe we can guarantee that if we don't obtain data, don't ask questions, don't train researchers, don't seek answers, we will continue to waste health care dollars, will continue to support waste, and will run real risks of creating a health care system so driven by cost control and profit maximization efforts that quality is sure to suffer and access sure to decline.

Senator INOUYE. How do you respond to a suggestion that with increased involvement of the Government, the greater the risk of socialized medicine?

Mr. FEIN. Involvement in funding for health care services is primarily particular target population groups and most particularly Medicare and Medicaid. It is hard for me to respond with other than anger at the suggestion that a social insurance program such as Medicare, built on the traditions of a social insurance program such as Social Security, can lead us to socialism or socialized medicine. Rather the other way around.

By preserving a health care sector that makes its resources available to all, including those who do not have the income to buy them on the open market, we are far more likely to strengthen existing institutions and to preserve the best of what is in medicine, rather than to destroy the whole thing.

I think a democratic society protects itself best by making those things that are necessary for a good life available to all members of the society, not by setting up classes in which some can buy health care and life itself and others can't.

Senator INOUYE. I am certain you are aware that in the fifties when we were discussing and debating Medicare, socialized medicine was a major concern of the American Medical Association.

Mr. FEIN. I am aware of that. I was a staff member on President Truman's Commission on the Health Needs of the Nation, and I recall quite vividly that President Truman was accused of being in favor of communism, socialism, and other isms of that type, a charge which was not accurate.

Senator INOUYE. I thank you very much, sir.

STATEMENT OF PENNY BELLAMY, CHAIR, PUBLIC AFFAIRS, PLANNED PARENTHOOD OF CONNECTICUT, REPRESENTING PLANNED PARENTHOOD FEDERATION OF AMERICA

Senator INOUYE. Our next witness is Penny Bellamy, chair of public affairs, Planned Parenthood Federation of America.

Welcome, Ms. Bellamy.

Ms. BELLAMY. Thank you. Good morning.

I am Penny Bellamy, the public affairs chair for Planned Parenthood of Connecticut, but I am representing Planned Parenthood Federation of America here this morning, the Nation's oldest and largest voluntary family planning organization, and am appearing here this morning on behalf of Faye Wattleton, the president of Planned Parenthood, who had hoped to be here today.

It is always an honor for Planned Parenthood to appear before this subcommittee. This subcommittee and its leadership has been unwavering in its support for the National Family Planning Program, title X of the Public Health Service Act, and Planned Parenthood is very grateful for that support.

Title X is the backbone of the national family planning clinic network that provides medical and education services to low-income women and adolescents. It is one of relatively few public health programs to remain a categorical program. The Congress wisely resisted efforts by the administration to fold title X into a block grant, which would blur its identity and inevitably result in a reduced stream of public funds for critical family planning services.

Title X is also the one Federal program that demonstratably serves to reduce the need for abortion. Those who oppose abortion have forced vote after vote in Congress each year on negative proposals. Title X remains as the one positive effort by Congress to do something concrete and quantifiable to reduce abortion in the United States.

In one recent year alone, the National Family Planning Program is estimated to have averted 800,000 unintended pregnancies, including 425,000 among teenagers. Had these pregnancies occurred, they would have produced an estimated 282,000 additional births and 433,000 abortions in that one year alone.

A recent poll by the Lou Harris Organization indicated that an overwhelming majority of Americans, 84 percent, consider teen pregnancy to be a major national problem. Greater emphasis and availability on birth control to teenagers is one means of addressing that problem that Americans widely support, according to this Harris poll, and with your permission, Senator, I would like to provide a copy for the record.

Senator INOUYE. Without objection, it will be made part of the record along with your statement.

Ms. BELLAMY. Thank you.

[The statement follows:]

STATEMENT OF PENNY BELLAMY

INTRODUCTION

I am Faye Wattleton, President of the Planned Parenthood Federation of America (PPFA). I am representing the more than 17,000 volunteers and staff who run our 187 affiliates in 46 states and the District of Columbia, the 250,000 individuals who contribute to our organizations, and above all, the more than 3 million women and men who are served by our clinics each year. I want to thank you and this subcommittee for the opportunity to present our views on the need to strengthen the national family planning program and expand research in contraceptive technology.

As you know, Title X of the Public Health Service Act is the core of our national family planning clinic network that provides subsidized services to low-income women and teenagers. For the sixth year in a row, the Administration is once again seeking Title X's repeal in favor of its embodiment in a primary care block grant to states. This would not only eliminate the only specific source of funding for family planning services but also would place family planning services in direct competition with other basic health services for an ever dwindling pot of federal money. We are confident that Congress will continue its long-standing, bipartisan commitment to family planning this year and reauthorize the Title X program basically in its current form.

Although we are aware of the budgetary pressures on this committee, we are requesting that you restore funding for Title X. We do so because Title X's record of accomplishment shows that an investment in this program results in tremendous savings in health care and social services costs that the government would be obliged to pay.

Irrespective of a final ruling on its legality, the Gramm-Rudman-Hollings budget law has changed the political landscape for some time to come. Congress has a choice: it can make the tough spending decisions, reallocating scarce federal dollars into those programs which have proven successful and cost effective, or it can abdicate this responsibility, allowing the budget ax to fall evenly on all programs, regardless of their ability to produce budgetary savings over the long run.

We urge the Congress and this committee to assume the responsibility entrusted to you by those you represent by investing in the Title X program - one federal program where a relatively small increase in spending this year can result in tremendous savings in health care and social services costs to the government for many years to come.

Similarly, we also urge you to increase support for population research, specifically authorized under Title X and Section 301 of the Public Health Service Act, and to place particular emphasis on research leading to the development of new contraceptive technology. Recent distressing developments make this an urgent matter.

Of 36 million American women who are seeking to avoid pregnancy, three million are using no contraception, and another three million are using the least effective methods. The most common reason cited for using no method is the fear of possible side effects. It is critical that further studies be pursued to identify and counteract the specific risk factors that do exist. At the same time, intensified research in the development of new and improved methods of contraception could greatly enhance our ability as a society to lower the staggering 55 percent incidence of unintended pregnancy that still exists in this country today.

FAMILY PLANNING SERVICES

Mr. Chairman, the Title X program prevents unintended pregnancies, reduces the need for abortion, and provides basic health services to a large group of medically underserved women. It is estimated that approximately 800,000 unintended pregnancies - 425,000 among teenagers - were averted in one year alone (1981) as a direct result of the national family planning program. Had these pregnancies occurred, there would have been an estimated 282,000 additional births and about 433,000 more abortions in that year alone.

Moreover, in addition to providing basic contraceptive services (including natural family planning) and infertility diagnosis, Title X clinics also offer health screening assessments and either simple treatments or referral for anemia, hypertension, cervical and breast cancer, sexually transmitted diseases, kidney dysfunction and diabetes. The Reagan administration has called family planning "a vital health care program for women in this country." Clinics such as those financed through Title X often are the first place women - and especially teenagers - receive formal medical care.

As I have already noted Mr. Chairman, these services are made available at a considerable cost-savings to the government. Each dollar invested in family planning yields a two-dollar savings in the next year alone in health and welfare costs associated with pregnancy and childbirth. For teenagers the ratio is even higher: the federal government saves three dollars for every federal dollar invested in family planning. A report by the Center for Population Research released in February, 1986 set at $16.7 billion the 1985 cost to taxpayers of public services required to maintain families begun by teen mothers. Clearly, federal investments in voluntary contraceptive services are wise and prudent.

Despite the accomplishments of the Title X program, a tremendous number of women continue to go unserved. In 1981, there were 9.5 million poor women and five million teenagers at risk of unintended pregnancy. In 1983, the organized clinic system made family planning services available to 5 million women, 1.6 million of whom were teenagers and 80 percent of whom were low-income, i.e., below 150 percent of the poverty line. Title X continues to be the single largest source of funds for this network, comprising 34 percent of the total federal and state expenditures. Primarily through the help of Medicaid or other special arrangements, an additional 3.2 million women were able to obtain contraceptive services from private physicians. The rest were left without health care.

Unfortunately, the growing need for the contraceptive and basic reproductive health services provided by Title X has been met by a shrinking federal commitment of funds. In FY 1981, Title X was funded at $166 million. The effects of the 25 percent cut later that year and in FY 1982 were severe. Straining to avoid turning patients away, clinics around the country were forced to reduce the scope of their services, especially community outreach to "hard to serve" patients. They have found it difficult to maintain, much less expand, educational programs geared toward adolescents and their parents -- exactly the sorts of programs Congress wants from Title X, as recent congressional debates have demonstrated. A $16 million increase in FY 1984 and an additional $2.5 million for FY 1985 - brought Title X funding from $124 million in FY 1982 to $142.5 million in FY 1985. The level was frozen at $142.5 million in FY 1986.

The 4.3 percent reduction on March 1, and the prospect of cuts two or three times that size if Congress fails to make spending and revenue decisions consistent with its deficit reduction goals, clearly jeopardize the future of Title X. Neither individual and societal health, nor the social and economic consequences of unintended pregnancy and childbirth, have not been sensitive to Congressional budgetary exigencies. Accordingly, individual family planning clinics, hospital programs and others are searching, often in vain, for ways of adequately serving their patient population's needs.

Looking beyond the statistics and the proven record of accomplishment of Title X grantees, I believe the time has come to question the motives and the illogical proposals of those who oppose family planning. These attacks and calls to curtail or eliminate the delivery of family planning services come almost exclusively from organizations whose primary mission is to once again criminalize abortion. Is it possible that they don't realize that eliminating the Title X program would lead to an increase in abortions? That deterring teenagers from seeking contraceptives by imposing a parental consent or notification requirement would lead to still more pregnancies among teenagers and more abortions? That excluding medically responsible individuals and organizations from the Title X program or from contracting for delivery of family planning services at home or overseas will lead only to more abortions?

The lines have been drawn on the abortion debate in this country and in the Congress. And yet, some members of Congress, though still not enough, who vote consistently to limit abortion funding, are among the strongest supporters of family planning, obviously recognizing the need to curb unintended pregnancies and thereby reduce abortions.

While divisions on the question of abortion persist, I submit to you that we must all work together in supporting the means to reduce the need for abortion, a personal decision that no one makes without careful consideration and few choose without some measure of sorrow.

RESEARCH

Title X currently authorizes research in the reproductive sciences, social and behavioral studies, contraceptive development and contraceptive evaluation. The National Institute of Child Health and Human Development (NICHD) administers all these areas of research, which together are presently funded at approximately $105 million. Perhaps part of the reason this area of study receives such a low priority at the National Institutes of Health (NIH) is that NIH is mainly disease-oriented, whereas research of this type mainly benefits healthy people. The irony, of course, is that the strides we are able to make as a society in this field directly touch the lives of virtually all Americans, not to mention the rest of the world, for which NIH is the major source of research and contraceptive technology and development. Similarly, much of what we know today about the tremendous health, social and economic costs of adolescent pregnancy - to the adolescents and their families as well as society as a whole - has been generated by work in the social and behavioral research component. It is extremely important that greater financial support is given to all research in human reproduction and population.

We are especially concerned, however, about contraceptive research, with less than 10 percent of the current $105 million spent on "population research" going for contraceptive development. The recent decision by G. D. Searle and Company to cease all U.S. sales of its intrauterine devices (IUDs) by itself will severely curtail the choices American women and men have had to control their fertility. The reason cited by Searle for withdrawing its IUDs from the market, their increasing difficulty in obtaining product liability insurance, sends ominous signals to any company, agency or researcher that is currently trying to develop better, safer methods of contraception. There are nearly 100 new varieties of contraceptives in various stages of development, including several at NICHD. Some companies even have products ready for field trials but cannot get the insurance so that testing may proceed. With half of the pregnancies in this country unintended, the narrowing of effective choices of contraception, along with the potential increase in unplanned pregnancies and abortions that likely will result from the loss of IUD's, constitutes a national tragedy.

There will probably never be a single perfect contraceptive, since individual circumstances change over a lifetime, as do family planning goals and attitudes. Yet in spite of the universal interest in better contraception, federal support for development of new or improved methods, as well as for the evaluation of the safety and effectiveness of current ones, has actually declined since FY 1981. Just four years ago, the Office of Technology Assessment (OTA) recommended that an additional $20 million annually in federal funding for contraceptive technology, noting that available research opportunities are only waiting to be exploited. Mr. Chairman, I would like to insert into the record two recent articles from Family Planning Perspectives, published by The Alan Guttmacher Institute, on these leads and the availability of funding for some of these leads, which should give you an excellent idea of how close we are to better contraception. This is not a field which needs a single, massive injection of funds - rather, slow, steady funding is required to bring some of these leads to fruition.

As you have recently heard from Administration testimony, NICHD continues to make last year's proposed Contraceptive Development Initiative a priority. However, prior funding commitments may make that initiative less of a reality than planned. Mr. Chairman, we need new methods of contraception. And we need to reassure ourselves about the safety and efficacy of current ones. We applaud NICHD's efforts in this area. At the same time, we strongly urge you to endorse a specific increase for contraceptive development and evaluation, through an earmark or committee report directives.

SUMMARY AND RECOMMENDATIONS

The highest point reached in Title X funding was an appropriation of $166 million in 1981. (This figure was cut back by a rescission to $162 million, the actual amount by which the program was funded that year.) Accounting for inflationary increases alone, the current level of Title X funding should be approximately $210 million. Given the reality mandated by the largest peacetime deficit in history and the Gramm-Rudman-Hollings mandate, we support funding for FY 1987 at the highest possible amount, noting that the Senate authorizing committee has approved a funding level of $145.7 million, and the House authorizing committee has approved a level of $147 million. This figure would merely restore funding for the program to levels attained well before 1980, not accounting for inflation. For the Center for Population Research, PPFA recommends a special supplementary fund of $20 million in order to boost the Contraceptive Development Initiative.

We thank the committee for its support in the past. In this year of focusing on cost-effective programs, we believe that continued support for Title X and for population research should be high priorities.

Ms. **Bellamy**. In Connecticut, Planned Parenthood is the direct grantee for the title X program. About $1.2 million is distributed among seven providers at 12 locations. In 1985, 166,000 women in Connecticut were estimated as needing subsidized family planning services, and 45,000 of those were sexually active teens. Less than one-half the women in need, or only about 48 percent, actually receive the services that they need, and in your State of Hawaii, Planned Parenthood receives nearly $200,000 a year, about 29 percent of the total planned parenthood budget from title X. Additional title X money is used by the State health department to provide family planning services on the six islands.

Each dollar invested in family planning yields a $2 saving in the next year alone in health and welfare costs associated with pregnancy and childbirth. For teenagers, that ratio is even higher, $3 saved for every $1 invested. A report by the Center for Population Options in February set at $16.7 billion the cost to taxpayers of services required to respond to the unintended pregnancies among American teenagers in 1985 alone.

Unfortunately, continuing pressure for spending cuts has taken a toll on the title X program. In fiscal year 1981, the Congress allocated $166 million for family planning. Here we are 5 years later with only $137.6 million for the program. Unless the cuts stop and funds are restored, the costly problem of unwanted pregnancy is likely to further threaten deficit reduction efforts through massive increases in health and welfare entitlement spending.

I might also add that we are anxiously awaiting Senate action on the title X reauthorization bill which was ordered reported from the Labor and Human Resources Committee last December.

I would like to say just a word about contraceptive research because, like title X, it represents a prudent investment which will ultimately reduce Government costs. Title X authorizes research in reproductive sciences and in contraceptive development and evaluation, but of the $105 million spent on population research by NICHD, less than 10 percent goes for contraceptive development.

We need new methods of contraception and we need to reassure ourselves about the safety and reliability of those currently in use.

We urge this committee to endorse a specific increase for contraceptive development and evaluation through an earmark or report language.

Planned Parenthood understands the enormous pressures upon the Congress to reduce the deficit. We sympathize as you try to balance health and social needs against the demand for more military spending. We urge you to fund title X for fiscal year 1987 at a level consistent with that approved by the authorizing committees for this year, with a supplemental fund of $20 million to boost the contraceptive development initiative.

In this year of focusing on cost-effective programs, continued support for title X and for population research should be high priorities.

Thank you.

Senator INOUYE. Thank you very much.

I am certain you are aware that this subcommittee has been most supportive of your efforts, and your Senator wanted to be here but he is under the weather right now.

Ms. BELLAMY. Thank you for your attention this morning.

Senator INOUYE. Thank you very much.

STATEMENT OF JAMES L. DEGER, GOVERNMENT INFORMATION DIRECTOR, AMERICAN LIFE LEAGUE

Senator INOUYE. Our next witness is James L. Deger, government information director, American Life League.

Mr. DEGER. Good morning. Thank you.

Senator Inouye, my name is Jim Deger. I am government information director for the American Life League, a national Christian-based prolife organization.

We wish to address here today the title X program of the U.S. Public Health Service. Since the inception of title X in 1970, congressional support of subsidized birth control programs has been based on four assumptions about birth control: first, that it prevents abortion; second, that it eliminates adverse outcomes from unintended pregnancies; third, it does not stimulate sexual activity; and fourth, improves reproductive health.

These assumptions have been repeated time and again before House and Senate authorization and appropriation committees, without any documentation to support them. Birth control proponents have long known that abortion is more frequent among birth control users. Studies stretching back to the 1930's, many funded by Planned Parenthood, have documented this fact.

Further, studies from Sweden and England verify that women on the pill experience more sexual partners. Dr. Robert Kistner of the Harvard Medical School said in 1977 that "About 10 years ago, I declared that the pill would not lead to promiscuity. Well, I was wrong."

Public health professionals like Kistner acknowledge that the change in unmarried sexual behavior over the past 15 to 20 years has been facilitated by increased birth control availability. This is not really that surprising, for deep within Planned Parenthood's Alan Guttmacher report on teen fertility in developed nations is a discussion about the role which Scandinavian countries have played in providing a model for social change in the United States.

The authors state that with so many out-of-wedlock births in Sweden, 40 percent, the desirability of marital births or childbearing have disappeared. They then note with a degree of approval that this process is beginning in the United States.

> These, as well as other changes, perhaps implied that the United States will be following suit in eventually adopting more rational attitudes toward adolescent sexuality.

Congress in essence has been funding the demise of the American family. This policy is the brainchild of the largest recipient of title X funds, the Planned Parenthood Federation of America, an organization which has long shown an interest in manipulating or even breaking the law. Let me state several examples.

First, lawbreaking. In a 1984 publication authored by Faye Wattleton, president of Planned Parenthood, and six others, we find:

> Family planning associations and other nongovernmental organizations should not use the absence of law or the existence of an unfavorable law as an excuse for inaction. Action outside the law or even in violation of it is part of the process of stimulating change.

Second, manipulation of the law. At a Planned Parenthood conference in 1971, cochaired by Dr. Louis Helman, the Federal administrator of title X, Planned Parenthood's own Christopher Tietze asked if the Dingell amendment, section 1008 of title X, would disrupt any abortion operation. Ruth Roemer of the University of California, Los Angeles answered that the Dingell amendment was vaguely worded and that efforts were underway to circumvent its intent.

The General Accounting Office [GAO] report of 1983 has shown that Ms. Roemer and her colleagues were successful.

Last year when the Kemp amendment was suggested as a way to correct the problems indicated by the GAO report, planned parenthood tried to hide their abortion promotion behind the shield of birth control in the first amendment. We all know that Catholic-affiliated organizations cannot receive title X funds because of their moral objections to artificial birth control. Why is it that Congress cannot in turn tell Planned Parenthood something similar: no taxpayer funds for abortion, abortion counseling, or abortion referral.

Planned Parenthood's manipulation reached a new high point last year with their release of their $80,000 Harris poll. What is more interesting for the public is what they didn't state when they released the poll.

For example, Planned Parenthood in their clinics have claimed that they must maintain a sneak policy, letting minors receive services without parental consent. Their poll shows that 48 percent of the parents polled support requiring consent, and 47 percent were opposed. This is a change from March 1984, when only 44 percent were in favor and 53 percent were opposed.

This change is even more significant in light of the response to a subsequent question, which asked what they thought would happen if the present policy continues. Fifty-three percent said it would increase pregnancies, and only 18 percent said that it would result in fewer pregnancies.

Finally, I would like to address briefly the assumption that this is an improvement in reproductive health. The use of modern birth control has been associated with an increase in venereal disease and the prevalence of infertility. The costs are borne by men and women with gonorrhea, ectopic pregnancy, pelvic inflammatory disease, and by their future children with chlamydia-induced pneumonia.

Chlamydia has a special association with the pill, namely, the claim by Howard Ory of the protective effect of the pill against this disease and the pelvic inflammatory disease. This claim was repeated by Ory and others from Planned Parenthood's Alan Guttmacher Institute in 1983.

However, in the journal of the American Medical Association in 1985, this claim was seriously challenged by Dr. A. Eugene Washington. He clearly indicated that studies show the opposite, namely, that there is a twofold to threefold increase in the prevalence of chlamydia with all contraceptive users.

In summary, it appears that the assumptions underlying the title X program have not been proven. They are, at the least, questionable, and at the most, false. To renew the program's funding without some safeguards to prevent abuse and provide adequate protection for children from health hazards would be amazing.

PREPARED STATEMENT

In additional comments to be submitted by the American Life League on or before May 20, a review of possible safeguards that can be implemented through the appropriations process will be provided. I ask that the record remain open for these comments.

Thank you very much, Mr. Chairman.

[The statement follows:]

STATEMENT OF JAMES L. DEGER

Mr. Chairman and Members of the subcommittee I am Jim Deger, Government Information Director for the American Life League, a national Christian based pro-life organization.

Since the inception of Title X in 1970, congressional support of subsidized birth control programs has been based on four assumptions about birth control: That it 1. prevents abortion; 2. eliminates adverse outcomes from unintended pregnancies; 3. does not stimulate sexual activity; and 4. improves reproductive health.

These assumptions have been repeated time and again before House and Senate authorization and appropriation committees without any documentation to support them. Amazingly, in spite of this lack of proof and with the rising incidence of out-of-wedlock births, sexually transmitted diseases, and abortions, Congress, since 1971, has provided $1.7 billion for the Title X program.

Birth control proponents have long known that abortion is more frequent among birth control users. Studies stretching back to the 1930's, many funded by Planned Parenthood, have documented this fact. Furthermore, studies from Sweden and England verify that women on the pill experience more sexual partners. Dr. Robert Kistner, of the Harvard Medical School and the Boston Hospital for Women said in 1977 that "About 10 years ago I declared that the pill would not lead to promiscuity. Well, I was wrong." Public health professionals like Kistner acknowledge that the change in unmarried sexual behavior over the past 15 to 20 years has been facilitated by increased birth control availability.

This is not really that surprising. Deep within Planned Parenthood's Alan Guttmacher Report on Teen Fertility in Developed Nations is a discussion about the role which Scandinavian countries have played in providing a model for social change in the United

States. The authors state that with so many out-of-wedlock births in Sweden (40 percent) the desirability of marital births or childbearing has disappeared. They then note, with a degree of approval that this process is beginning in the United States. "These as well as other changes perhaps imply that the U.S. will be following suit in eventually adopting more rational attitudes towards adolescent sexuality."

Congress in essence has been funding the demise of the American family. This policy is the brainchild of the largest recipient of Title X funds--the Planned Parenthood Federation of America--an organization which has long shown an interest in manipulating or even breaking the law. Let me state several examples.

First, law breaking. In a 1984 publication authored by Faye Wattleton, president of Planned Parenthood, and six others entitled The Human Right to Family Planning we find: "Family Planning Associations and other non-governmental organizations should not use the absence of law or the existence of an unfavorable law as an excuse for inaction; action outside the law, or even in violation of it, is part of the process of stimulating change."

Second, manipulation of the law. At a Planned Parenthood conference in 1971, co-chaired by Dr. Louis Helman, the federal administrator of Title X, Planned Parenthood's own Christopher Tietze, asked if the Dingell amendment (section 1008 of Title X which forbids abortion as a method of family planning under the program) would disrupt any abortion operations. Ruth Roemer, of UCLA, answered that the Dingell amendment was vaguely worded and that efforts were underway to circumvent its intent. She further stated that "There are obviously various accounting and technical devices which can be used so that the provision doesn't affect any abortion program adversely."

The General Accounting Office report of 1983 has shown that Ms. Roemer and her collegues were successful--through accounting methods and other technical procedures a number of Title X clinics receive funds and still perform abortions, counsel women for abortions, or refer for abortion services. The most blatant example cited is a clinic splitting the day between hours for abortions and hours for birth control dispensing. The same employees, paid through the Title X program, dispense birth control and assist in the abortion operation.

Last year, when the Kemp amendment was suggested as a way to correct the problems indicated by the GAO report, Planned Parenthood tried to hide their abortion promotion behind the supposedly protective shield of birth control and also the First Amendment. We all know that Catholic-affiliated organizations cannot receive Title X funds because of their moral objections to artificial birth control. Why is it that Congress cannot tell Planned Parenthood, the National Family Planning and Reproductive Health Association, and others something similar: No taxpayer funds for abortion, abortion counseling, or abortion referal.

Note that one of the birth controller's allies, the American Civil Liberties Union, has sued the Arlington Catholic Diocese for indulging in prohibited speech and receiving federal Title XX funds. The prohibited speech is talking about chastity. How can groups which try to restrict a church's right to talk about chastity and receive federal funds turn around and make the claim that their free speech on abortion, a medical procedure the Supreme Court in McRae v. Harris said is inherently different from all others, is being violated? Planned Parenthood and their allies have no right to try to hide their abortion promotion behind the First Amendment and still receive federal funds.

Planned Parenthood's manipulation reached a new high point last year when they announced their $80,000 Harris poll. What they didn't release from the poll were results opposite from their stated goals. For example in response to the question on what is the most important thing parents should do to prevent their teenage children from becoming pregnant or causing pregnancy, only 22 percent agree with directing children towards birth control--73 percent suggested other solutions.

Further, Planned Parenthood and their clinics have claimed that they must maintain a "sneak policy" of letting minors receive services without parental consent. Their poll shows that 48 percent of the parents polled support requiring consent and 47 percent opposed--this is a change from March 1984 when only 44 percent were in favor and 53 percent opposed. This change is even more significant in light of the response to the subsequent question which asked what they they thought would happen if the present policy continues: 53 percent said it would increase pregancies and only 18 percent said it would result in fewer pregnancies.

This brings me to the most recent health masquerade--school-based birth control outlets. While no adequate studies have been produced to show what effect these clinics have, Planned Parenthood and their allies are pushing forward with efforts to increase the number of these clinics. It is claimed that they reduced teen pregnancies. However, even a Planned Parenthood writer recently noted that the claimed decline cannot be determined as being due to increase in birth control availability or an increased reliance on abortion.

What then is the advantage of these clinics, if it can't be shown to be pregnancy reduction? It is simply to get more children using dangerous chemicals and devices. Miss Hill Young, an attendee at the October 1985 School Birth Control conference stated this very clearly: "We really keep a close hold on these kids," and "if they don't show up, we go get them. That's one of the advantages of being in school."

The advantage can't be one of the underlying assumptions of the Title X program--that is, improvement in reproductive health. The use of modern birth control has been associated with an increase in venereal disease and the prevalence of infertility. The costs are borne by both men and women with gonorrhea, ectopic pregnacy, urethritis, pelvic inflammatory disease, and by their future children with chlamydia-induced pneumonia, and conjunctivitis.

Due to the increase of premarital sexual intercourse associated with the increased use of oral contraceptives and IUDs, as reported in the *Johns Hopkins School of Hygiene and Public Health Journal*, the incidence of chlamydia has also increased. Infants born to mothers with chlamydia have a 50 percent chance of contracting the disease. Chlamydia has another association with the pill, namely the claim by Howard Ory, M.D. of the protective effect of the pill against this disease and pelvic inflammatory disease. This claim was repeated by Ory and others associated with Planned Parenthood's Alan Guttmacher Institute in 1983. However, in the *Journal of the American Medical Association* in 1985 this claim was seriously challenged by Dr. A. Eugene Washington. He clearly indicated that studies show the opposite, namely that there is a twofold to threefold increase in the prevalence of chlamydia with oral contraceptive users.

In summary, it appears that the assumptions underlying the Title X program have not been proven. They are at the least questionable and at the most false. With Title X now unauthorized since last year, it is the Appropriations Committee's decision whether this program should continue or not. If the Members here today wish to continue this program, that is their responsibility.

However, to renew the program's funding without some safeguards to prevent abuse relating to abortion performance and promotion, parental involvment and to provide adequate protection for children from health hazards would indeed be amazing. In additional comments to be submitted by American Life League on or before May 20, 1986, a review of possible safeguards that can be implemented through the appropriations process will be provided. I ask that the record remain open for these comments.

Thank you Mr. Chairman and the Members for your time.

Senator Inouye. Is it your contention that without Planned Parenthood, we would have less unintended pregnancies and less abortions?

Mr. Deger. In the 15 years since title X has been in operation, there has been a continued increase in teenage pregnancies and teenage abortions. There has not been a decline as claimed by the estimate of 800,000, and there is no evidence to support that claim. These are merely extrapolations from the number of clients served and also the supposed effectiveness of pills, intrauteran devices and other forms of contraceptives.

Senator Inouye. Since the record will be open, Ms. Bellamy, if you wish you may submit a statement to respond to Mr. Deger.

Ms. Bellamy. Thank you, Senator.

Senator Inouye. Thank you very much.

Mr. Deger. Thank you very much, Senator.

STATEMENT OF ELIZABETH M. BODNAR, REGISTERED NURSE, PRESIDENT, AMERICAN ASSOCIATION OF OCCUPATIONAL HEALTH NURSES

Senator Inouye. Our next witness is Elizabeth Bodnar, the president of the American Association of Occupational Health Nurses [AAOHN].

Ms. Bodnar. Good morning. Thank you, Senator Inouye.

Our request was for testimony on appropriations for the Occupational Safety and Health Administration [OSHA], and we beg your indulgence to make those comments during today's hearings, even though we had been scheduled under the Health Resources and Services Administration.

I am Betty Bodnar. I have been in occupational health nursing for over 25 years, serving as a technical consultant in medical services for Liberty Mutual Insurance Co., and I come here today as president of the American Association of Occupational Health Nurses.

Representing thousands of professional occupational health nurses in business and industry, we would like to express our appreciation to the subcommittee for this opportunity to share our concerns for the current and future role of occupational health nurses in the workplace and in workplace health care.

We are requesting members of the Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee to provide sufficient funding for the Occupational Safety and Health Administration to employ occupational health nurses on the administrative staff and to make this recommendation to the Secretary of Labor.

We in AAOHN are convinced that the absence of occupational health nurses from the decisionmaking and standard development process at OSHA produces a corresponding lack of understanding of how health services are implemented in the workplace with the result that there is a reduction or may be a less than best effective protection for our workers.

Occupational health nurses still are unrecognized for their key role in the occupational health and safety programs in achieving health care cost containment. We have expanded our traditional role to include health maintenance, health promotional campaigns as part of the crucial development of the history of the practice of occupational health nursing. Additionally, the delegation of management responsibilities to occupational health nurses has resulted in cost effective and efficient occupational health services in the workplace.

AAOHN has documented that in the majority of work settings, the occupational health nurses are the only onsite health professionals. More than 50 percent of our members practice without onsite physicians, and in 55 percent of those programs with physicians present, even they are only on a part-time basis. On the average, our occupational health nurse spends approximately one-half of his or her time providing such employee services as counseling, assessment of health conditions and problems, screenings, and also referring workers to their own physicians, and the other one-half of the time is spent in supervisory and administrative activities such as developing and conducting employee health educational programs and doing environmental assessment and monitoring.

Three-quarters of our health professionals have managerial decisionmaking responsibilities, and we can say with pride that the occupational health nurses are the first contact for most workers, and as a result, provide the majority front-line direct health care.

From the occupational health nursing basis, there are two perspectives absent from the OSHA policy development as we see it. First of all, occupational health nursing is concerned primarily with preventing, rather than just treating injury and illness.

Second, occupational health nursing provides what we call the real world perspective. This insight has been gained through the experience of being, in a majority of instances, the sole health care provider and having to maintain that delicate balance in the respective safety and health concerns of either employees or employers.

We applaud OSHA for the steps that they have taken to begin to recognize the significant contributions of the occupational health nurse in conserving, promoting, and restoring the health of workers, and this is most notable in the appointment of two nurses to the National Advisory Committee on Occupational Safety and Health [NACOSH] and also in the proposed amendments to include the professional occupational health nurse in the definition of health professional in the hazard communication standard.

On behalf of AAOHN, I thank Senator Inouye, Senator Weicker, and the other distinguished members of this subcommittee for their help in getting us to effect this resulting recognition of the occupational health nurse as a professional.

We in AAOHN believe that when occupational health nurses are brought into the mainstream of decisionmaking processes at all levels, that the health and safety of America's workers will be safeguarded; the economic interests of our Nation's employers will be protected; and the profession of occupational health nursing will receive recognition for its significant contribution to the delivery of health care.

We, as occupational health nurses, rise to the challenge to share in the prevention of disability and stand united and ready to serve our consumer publics. We thank you again for allowing us to present the deep concerns of our nearly 12,000 members of the American Association of Occupational Health Nurses.

PREPARED STATEMENT

Senator INOUYE. Thank you very much. I'm certain you can count on our help.

Ms. BODNAR. Thank you very much, Senator.

[The statement follows:]

STATEMENT OF ELIZABETH M. BODNAR

The American Association of Occupational Health Nurses, which represents thousands of professional occupational health nurses working in business and industry, wishes to express appreciation to members of the subcommittee for providing us with an opportunity to share with you AAOHN's concern about the current and future role of occupational health nurses in workplace health care.

We are requesting members of the Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee to provide sufficient funding for the Occupational Safety and Health Administration to employ occupational health nurses on its administrative staff and to make that recommendation to the Secretary of Labor.

AAOHN is convinced that the absence of occupational health nurses from the decision-making and standard-development process at OSHA produces a corresponding lack of understanding of how health services are implemented in the workplace. The result is a reduction in effective protection for workers.

Occupational health nurses are still largely unrecognized for their key role in implementing quality occupational health and safety programs and in achieving health care cost containment. The expansion of the traditional role of occupational health nurses to include health maintenance and health promotion programs is a crucial development in the history of our practice. In addition, delegation of management responsibilities to occupational health nurses has resulted in cost-effective and efficient occupational health services in the workplace.

AAOHN has documented that in the majority of work settings, occupational health nurses are the only onsite health professionals. Over 50 percent of AAOHN members practice without onsite physicians; in 55 percent of those programs where physicians are present, they are employed only part-time.

The average occupational health nurse spends about 49 percent of each day providing employee services such as counseling, assessment of health conditions/problems, screening and referring workers. The other half of the day is spent on supervisory/administrative activities (16 percent), developing and conducting employee health education programs (12 percent) and environmental assessment/monitoring. Over three-fourths of these health professionals have managerial decision-making responsibility. Occupational health nurses are the first contact for most workers and provide the majority of front line direct health care.

An occupational health nurse can provide two perspectives that are absent for OSHA policy development. First, occupational health nursing practice is concerned primarily with preventing rather than treating illness and injury. Secondly, the occupational health nurse can provide a "real-world" perspective. This insight has been gained through the experience of being, in a majority of instances, the sole health care provider and having to maintain the delicate balance between the respective health and safety concerns of employees and employers.

OSHA has recently taken steps to begin to recognize the significant contributions of occupational health nurses in conserving, promoting and restoring the health of workers. Specifically:

- appointment of two occupational health nurses to the National Advisory Committee on Occupational Safety and Health (NACOSH); and

- proposed amendment to include registered professional occupational health nurses in the definition of "health professional" in OSHA's Hazard Communication Standard.

We applaud the agency for these initiatives.

AAOHN wants to take this opportunity to thank Senators Inouye and Weicker and other distinguished members of this subcommittee for their assistance in the effort that resulted in this recognition of the occupational health nursing profession.

AAOHN believes that when occupational health nurses are brought into the mainstream of the decision-making process at all levels, the health and safety of America's workers will be safeguarded, the economic interests of the nation's employers will be protected, and the profession of occupational health nursing will receive recognition for its significant contributions to the delivery of health care in the workplace.

Thank you again for allowing us to present the concerns of the nearly 12,000 members of the American Association of Occupational Health Nurses.

STATEMENT OF CHARLES A. WALKER, PH.D., DEAN, COLLEGE OF PHARMACY, FLORIDA A&M UNIVERSITY

Senator INOUYE. Our next witness is Dr. Charles A. Walker, dean, School of Pharmacy, Florida A&M University.

Dr. Walker, welcome, sir.

Mr. WALKER. Mr. Chairman and members of the subcommittee, I am Charles A. Walker, dean of the College of Pharmacy and Pharmaceutical Sciences at Florida Agricultural and Mechanical University in Tallahassee, FL.

I appreciate the opportunity to represent the colleagues at my university and to share with you and the committee some of our unique programmatic research and professional activities in the college and university, many of which are of national significance.

I would like to share further the concerns that threaten to curtail this activity if a proper support base is not realized in the near future.

First, allow me to provide some background information relative to our health professions school and its importance nationally in terms of supplying health manpower personnel who are experts relative to medication and drug-related problems and diseases.

The pharmacy program at Florida A&M University is one of four such programs at historically black colleges and universities [HBCU]. For the past 10 years, Florida A&M has been the leading producer of black minority bachelor of science pharmacy practitioners. We have produced some 16 percent of the total out of some 72 schools and colleges in the Nation. Our college has also produced some 60 percent of all postbaccalaureate doctor of pharmacy black minority graduates, and most recently we became the only college of pharmacy at an HBCU to initiate the Ph.D. degree in the pharmaceutical sciences.

Since 1975, less than 15 black males and no black females have earned the Ph.D. in this very important basic science, while better than 2,000 have been awarded to majority and other minority candidates. Because of commitment, tradition, and concern, the College of Pharmacy at Florida A&M will positively impact this situation in the near future.

In addition to the structured programmatic contributions, our college has emphasized for the last 10 years strong research and professional activity of national and international significance. We have made new and important discoveries in health care that have led to the patenting of new drugs and the development of new techniques for the better treatment of patients.

Most recently through our south Florida affiliation, the clinical aspect of our program is serving as a national model for advising the elderly, especially the minority elderly and other medically underserved and noncompliance patients, about their prescription drugs. This is a national health crisis, and our college, due to its strong clinical component, is making a significant impact on the problem.

For the past 5 years, the research program has involved more than 10 percent of our 300 undergraduate students and all of our faculty and postbaccalaureate students. The strong research activity has resulted in our college being designated a center of excellence by the Board of Regents of the State of Florida.

Our college is especially noted for its accomplishments in the area of chronophysiology and chronopharmacology. While this is supported by the National Aeronautics and Space Administration and the National Institutes of Health, its significance is extremely important in terms of space travel, space labs, and even transmeridian air flights while on Earth. The possibility of developing chronobiotics and compounds that synchronize and desynchronize human subjects is being studied and advanced in our laboratories.

The importance of this research ranges from an extreme interest by our national defense to similar concerns relative to athletic performance when people travel across time zones. The June 1, 1983, Chronical of Higher Education edition wrote that:

> According to Dr. Walker at the Florida A&M University College of Pharmacy, their researchers are working to develop a drug that will make it possible for individuals to shift their circadian cycle from one time zone to another without harm.

This research has tremendous importance in medicine, especially in terms of the proper treating of patients with drugs for illnesses with minimal toxic side effects. The May 27, 1978, British Medical Journal, in an editorial relative to a recent international symposium hosted by the Florida A&M University College of Pharmacy wrote:

> The Florida A&M conference covered many topics from endocrinology and parasitology to neuropharmacology. Chronobiology is a new science, and chronotherapeutics may well be a new skill for clinicians to learn as the evidence accumulates on the importance of the timing of treatment for either the day or the hour.

We have faculty presently working on a unique project which involves microbial degradation of the fuel hydrazine. We have a group of faculty deeply involved in motion sickness research. We are presently the only academic unit, to our knowledge, proposing to synthesize and test new drugs for motion sickness. Syndicated columnist Carl Rowan wrote in August 1983 that "scientists in Florida A&M University's College of Pharmacy are working on the problem of trying to develop medicines to combat space sickness."

The college has established excellent research support from such agencies as the National Institutes of Health, National Aeronautics and Space Administration [NASA], ONR, Agency for International Development, and Department of Energy. Total committed research dollars generated by the faculty is at an all-time high of $11.8 million through the year of 1991.

The college is also involved in some special training programs. One such program is a summer Space Life Sciences Training Program between the College of Pharmacy at Florida A&M University and the J.F. Kennedy Space Center. Each summer from 1985 through 1992, our college will contract 30 college students nationwide to conduct research in the life sciences at NASA. This is a hands-on, 6-week program designed to increase the pool of future aerospace scientists. This is the only such program in the Nation.

Our college is one of the leading research institutions, but the quality and quantity of research and research training is seriously threatened due to the lack of adequate facilities. In its urban development plan, the city of Miami has donated to the university and the college real estate totaling approximately $4 million for the purpose of constructing a research facility in its new overtown redevelopment plan. Funds are needed at present to construct a facility and laboratory equipment, and we are requesting support in the amount of $5.6 million as matching for the support already contributed by Dade County and the city of Miami.

PREPARED STATEMENT

Mr. Chairman, I appreciate the opportunity to appear before this committee, and I thank you for allowing me to explain our program and our concerns and its importance as a national and international center for research.

[The statement follows:]

Statement of Charles A. Walker

TO CHAIRMAN WEICKER AND MEMBERS OF THE SUB-COMMITTEE. I AM CHARLES A. WALKER, DEAN OF THE COLLEGE OF PHARMACY AND PHARMACEUTICAL SCIENCES AT THE FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY IN TALLAHASSEE, FLORIDA. I APPRECIATE THE OPPORTUNITY TO REPRESENT THE COLLEAGUES OF MY UNIVERSITY AND SHARE WITH YOU AND THE COMMITTEE SOME OF OUR UNIQUE PROGRAMMATIC, RESEARCH AND PROFESSIONAL ACTIVITIES IN THE COLLEGE AND UNIVERSITY, MANY OF WHICH ARE OF NATIONAL SIGNIFICANCE. I WOULD LIKE TO SHARE FURTHER CONCERNS THAT THREATEN TO CURTAIL THIS ACTIVITY, IF A PROPER SUPPORT BASE IS NOT REALIZED IN THE NEAR FUTURE.

FIRST, ALLOW ME TO PROVIDE SOME BACKGROUND INFORMATION RELATIVE TO OUR HEALTH PROFESSIONS SCHOOL AND ITS IMPORTANCE NATIONALLY IN TERMS OF SUPPLYING HEALTH MANPOWER PERSONNEL WHO ARE EXPERTS RELATIVE TO MEDICATION AND DRUG RELATED PROBLEMS AND DISEASES. THE PHARMACY PROGRAM AT FLORIDA A&M UNIVERSITY IS ONE OF FOUR (4) SUCH PROGRAMS AT HISTORICALLY BLACK COLLEGES AND UNIVERSITIES (HBCU's). FOR THE PAST TEN YEARS, FLORIDA A&M UNIVERSITY (FAMU) HAS BEEN THE LEADING PRODUCER OF BLACK MINORITY B.S. PHARMACY PRACTITIONERS. WE HAVE PRODUCED SOME 16% OF THE TOTAL OUT OF SOME 72 SCHOOLS AND COLLEGES IN THE NATION. OUR COLLEGE HAS PRODUCED SOME 60% OF ALL POST-BACCALAUREATE DOCTOR OF PHARMACY BLACK MINORITY GRADUATES. MOST RECENTLY, WE BECAME THE ONLY COLLEGE OF PHARMACY AT THE HBCU's TO INITIATE THE PH.D. DEGREE IN THE PHARMACEUTICAL SCIENCES. SINCE 1975 LESS THAN 15 BLACK MALES AND NO BLACK FEMALES HAVE EARNED THE PH.D. IN THIS VERY IMPORTANT BASIC SCIENCE, WHILE BETTER THAN TWO THOUSAND HAVE BEEN AWARDED TO MAJORITY AND OTHER MINORITY CANDIDATES. BECAUSE OF COMMITMENT, TRADITION AND CONCERN, THE COL-

LEGE OF PHARMACY AT FAMU WILL POSITIVELY IMPACT THIS SITUATION IN THE NEAR FUTURE. IN ADDITION TO THE STRUCTURED PROGRAMMATIC CONTRIBUTIONS, OUR COLLEGE HAS EMPHASIZED – FOR THE PAST TEN YEARS – STRONG RESEARCH AND PROFESSIONAL ACTIVITY OF NATIONAL AND INTERNATIONAL SIGNIFICANCE. WE HAVE MADE NEW AND IMPORTANT DISCOVERIES IN HEALTH CARE THAT HAVE LED TO THE PATENTING OF NEW DRUGS AND THE DEVELOPMENT OF NEW TECHNIQUES FOR THE BETTER TREATMENT OF PATIENTS. MOST RECENTLY, THROUGH OUR SOUTH FLORIDA AFFILIATION, THE CLINICAL ASPECT OF OUR PROGRAM IS SERVING AS A NATIONAL MODEL FOR ADVISING THE ELDERLY, ESPECIALLY THE MINORITY ELDERLY AND OTHER MEDICALLY UNDER SERVED AND NON-COMPLIANCE PATIENTS, ABOUT THEIR PRESCRIPTION DRUGS. THIS IS A NATIONAL HEALTH CRISIS AND OUR COLLEGE, DUE TO ITS STRONG CLINICAL COMPONENT, IS MAKING A SIGNIFICANT IMPACT ON THE PROBLEM.

FOR THE PAST FIVE YEARS, THE RESEARCH PROGRAM HAS INVOLVED MORE THAN 10% OF OUR 300 UNDERGRADUATE STUDENTS AND ALL OF OUR FACULTY AND POST-BACCALAUREATE STUDENTS. THE STRONG RESEARCH ACTIVITY HAS RESULTED IN OUR COLLEGE BEING DESIGNATED A "CENTER OF EXCELLENCE" BY THE BOARD OF REGENTS OF THE STATE UNIVERSITY SYSTEM. OUR COLLEGE IS SPECIFICALLY NOTED FOR ITS ACCOMPLISHMENTS IN THE AREA OF CHRONOPHYSIOLOGY AND CHRONOPHARMACOLOGY. WHILE THIS WORK IS SUPPORTED BY THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA) AND THE NATIONAL INSTITUTES OF HEALTH (NIH), ITS SIGNIFICANCE IS EXTREMELY IMPORTANT IN TERMS OF SPACE TRAVEL, SPACE LABS, AND EVEN TRANSMERIDIAN AIR FLIGHTS WHILE ON EARTH. THE POSSIBILITY OF DEVELOPING CHRONOBIOTICS AND COMPOUNDS THAT CAN SYNCHRONIZE AND DESYNCHRONIZE HUMAN SUBJECTS IS BEING STUDIED AND ADVANCED IN OUR LABORATORIES. THE IMPORTANCE OF THIS RESEARCH RANGES FROM AN EXTREME INTEREST BY OUR NATIONAL DEFENSE TO SIMI-

LAR CONCERNS RELATIVE TO ATHLETIC PERFORMANCE WHEN PEOPLE TRAVEL ACROSS NEW TIME ZONES. THE JUNE 1, 1983 CHRONICLE OF HIGHER EDUCATION WROTE THAT, "ACCORDING TO DR. WALKER AT THE FAMU COLLEGE OF PHARMACY, THEIR RESEARCHERS ARE WORKING TO DEVELOP A NEW DRUG THAT WILL MAKE IT POSSIBLE FOR INDIVIDUALS TO SHIFT THEIR CIRCADIAN CYCLE FROM ONE TIME ZONE TO ANOTHER, WITHOUT HARM."

THIS RESEARCH HAS TREMENDOUS IMPORTANCE IN MEDICINE, ESPECIALLY IN TERMS OF THE PROPER TREATING OF PATIENTS WITH DRUGS FOR ILLNESSES WITH MINIMAL TOXIC SIDE EFFECTS. THE MAY 27, 1978 BRITISH MEDICAL JOURNAL, IN AN EDITORAL RELATIVE TO A RECENT INTERNATIONAL SYMPOSIUM – HOSTED BY THE FAMU COLLEGE OF PHARMACY WROTE, "THE FLORIDA A&M CONFERENCE COVERED MANY TOPICS FROM ENDOCRINOLOGY AND PARASITOLOGY TO NEUROPHARMACOLOGY. CHRONOBIOLOGY IS A NEW SCIENCE AND CHRONOTHERAPEUTICS MAY WELL BE A NEW SKILL FOR CLINICIANS TO LEARN AS THE EVIDENCE ACCUMULATES OF THE IMPORTANCE OF THE TIMING OF TREATMENT FOR EITHER THE DAY OR THE HOUR."

WE HAVE FACULTY PRESENTLY WORKING ON A UNIQUE PROJECT WHICH INVOLVES THE MICROBIAL DEGRADATION OF THE FUEL HYDRAZINE. WE HAVE A GROUP OF FACULTY DEEPLY INVOLVED IN MOTION SICKNESS RESEARCH. WE ARE PRESENTLY THE ONLY ACADEMIC UNIT, TO OUR KNOWLEDGE, PROPOSING TO SYNTHESIZE AND TEST NEW DRUGS FOR MOTION SICKNESS. SYNDICATED COLUMNIST CARL ROWAN WROTE IN AUGUST OF 1983 THAT: "SCIENTISTS IN FAMU's COLLEGE OF PHARMACY ARE WORKING ON THE PROBLEM OF TRYING TO DEVELOP MEDICINES TO COMBAT SPACE SICKNESS."

THE COLLEGE HAS ESTABLISHED EXCELLENT RESEARCH SUPPORT FROM SUCH AGENCIES AS NIH, NASA, ONR, AID, AND DOE. TOTAL COMMITTED RESEARCH DOLLARS GENERATED BY FACULTY IS AT AN ALL TIME HIGH OF $ 11.8 MILLION THROUGH THE YEAR 1991. THE COLLEGE IS ALSO INVOLVED IN SOME SPECIAL TRAINING PROGRAMS. ONE SUCH PROGRAM IS THE SUMMER

SPACE LIFE SCIENCES TRAINING PROGRAM, BETWEEN THE COLLEGE OF PHARMACY AT FAMU AND THE J.F. KENNEDY SPACE CENTER. EACH SUMMER, FROM 1985 THROUGH 1992, FAMU WILL CONTRACT 30 COLLEGE STUDENTS NATIONWIDE TO CONDUCT RESEARCH IN THE LIFE SCIENCES AT NASA. THIS IS A HANDS-ON, SIX WEEKS PROGRAM DESIGNED TO INCREASE THE POOL OF FUTURE AEROSPACE SCIENTISTS. THIS IS THE ONLY SUCH PROGRAM IN THE NATION.

OUR COLLEGE IS ONE OF THE LEADING RESEARCH INSTITUTIONS, BUT THE QUALITY AND QUANTITY OF RESEARCH AND RESEARCH TRAINING IS SERIOUSLY THREATENED DUE TO THE LACK OF ADEQUATE FACILITIES. IN ITS URBAN DEVELOPMENT, THE CITY OF MIAMI HAS DONATED TO THE UNIVERSITY FOR THE COLLEGE OF PHARMACY REAL ESTATE TOTALING APPROXIMATELY 4 MILLION DOLLARS FOR THE PURPOSE OF CONSTRUCTING A RESEARCH FACILITY IN THEIR CITY. FUNDS ARE NOW NEEDED TO CONSTRUCT, STAFF, AND EQUIP THIS LABORATORY.

I APPRECIATE THE OPPORTUNITY TO APPEAR BEFORE THE COMMITTEE AND I THANK YOU FOR ALLOWING ME TO EXPLAIN OUR PROGRAMS AND OUR CONCERNS RELATIVE TO THEIR CONTINUED EXISTENCE.

Senator INOUYE. You have a most impressive record, sir.

Mr. WALKER. Thank you.

Senator INOUYE. Have you discussed this appropriation for building with your Florida Senators?

Mr. WALKER. Yes; we have. And, of course, they are supportive and will supply some matching dollars, but we are here because of the national and international ramifications of the work that we're doing.

Senator INOUYE. We will keep this in mind, sir.

Mr. WALKER. Thank you.

Senator INOUYE. Thank you very much.

STATEMENT OF CHARLES R. MODICA, J.D., CHANCELLOR, ST. GEORGES UNIVERSITY SCHOOL OF MEDICINE, GRENADA, WEST INDIES

Senator INOUYE. Our next witness is Mr. Charles Modica, chancellor of St. Georges University School of Medicine, Grenada, West Indies.

Welcome, sir.

Mr. MODICA. Mr. Chairman, I am pleased to appear before you today to speak about St. Georges University School of Medicine in Grenada to discuss the issue of Federal support for students attending foreign medical institutions. I am Charles Modica, chancellor of St. Georges University School of Medicine in Grenada.

Since St. Georges was founded in August 1976, nearly 800 students have graduated with degrees in medicine. Many have returned to the United States to practice in underserved areas, especially in inner city teaching hospitals that treat large numbers of low-income and indigent populations. In fact, 80 to 90 percent of these residency positions are filled by graduates of foreign medical schools. There would be a significant problem in handling the patient load in many of these hospitals without foreign graduates.

The journal of the American Medical Association, in its January 18, 1985, issue, reported that St. Georges University School of Medicine have the highest initial pass rate in the United States qualifying examination than any other major foreign medical school in the world. As each class at St. Georges finishes its second year of medical education, approximately one-third of that class transfers to U.S. medical schools to complete their education. This, too, represents the highest rate of any foreign medical school in the world.

The list of hospitals, many affiliated with U.S. medical schools, where most foreign-trained medical graduates have current residencies or have completed their specialties and subspecialties includes almost every State in the Union. St. Georges graduates are participating in 297 different training programs in 192 hospitals. St. Georges graduates are, for the most part, doing equal or better than many U.S. graduates. They are licensed and practice in most States.

Mr. Chairman, I mention the above points for several reasons, but mostly to dispel the myth that all students trained at foreign medical schools are second rate. Further, I want to make it clear that the same holds true for the institutions at which these students train. In this brief exchange, I hope to set St. Georges apart from other institutions that have been accused of providing less than adequate medical education.

St. Georges and other offshore institutions have faced an organized effort by several U.S. medical societies and organizations to diminish the credibility of their graduates and restrict the entry of those who have completed its educational process. This organized effort includes restricting admission to licensing examinations, refusal to issue licensing applications, restricting admissions to residency programs, and insisting on separate examinations from those given to U.S. medical students and graduates.

Could a primary reason for this be that when in 1979 St. Georges students took the same exam that U.S. medical students took, they scored so well compared to the U.S. students? In fact, that exam was not given to foreign medical graduates after that year.

Mr. Chairman, recently Congress has considered several proposals to reduce or eliminate Medicare graduate medical education [GME] funding for the training of students educated in foreign medical institutions. As you are most likely aware, the recently passed budget reconciliation bill requires that a foreign-trained student pass the foreign medical graduation examination in the medical sciences, known as the FMGEMS, to qualify for GME funding. Although this examination is, in fact, more difficult than the national boards that American students take, we at St. Georges believe this is a fair compromise and does not arbitrarily discriminate against the student, based solely on his or her place of education. Therefore, we applaud Congress' discretion in making this provision fair.

I come before you today to request that in your subcommittee's consideration for funding of Federal programs for the health professions and student aid, particularly guaranteed student loans, that you take these aforementioned statements into consideration. The Education Department has made several attempts to administratively cut off guaranteed student loans to U.S. residents attending foreign medical schools.

Should a proposal like this develop during your consideration, I am hopeful that you will use the same discretion that the reconciliation conference yielded, a fair and equitable approach to the pursual of funds for all U.S. citizen students, notwithstanding their choice of United States or foreign schools.

Further, while our students or institutions do not receive a great deal of the health professions' resources allocated by your panel, we urge that you resist the overtures of select groups in organized medicine to discriminate against graduates of schools abroad, and St. Georges in particular.

In the event that there are cuts suffered, I would enter a plea for equality for all U.S. medical students, whether they study in the continental United States or are forced to study elsewhere.

While the medical monopoly of organized medicine criticizes foreign medical schools, it is imperative for you to note and allow representatives of foreign schools to address these allegations on a continuing basis. The American model of medical education, while clearly the most expensive in the world, may not be producing physicians of the quality of some foreign schools with far less funding. For instance, at St. Georges, we spend one-quarter the amount of an American medical school on site visit teams, including the State of New York team, which came down to Grenada, and also saw clinical clerks operating in New York hospitals, found them to be, quote, indistinguishable from the median United States trained students.

PREPARED STATEMENT

Thank you for the opportunity to present our views. I am happy to respond to any questions you may have.

[The statement follows:]

STATEMENT OF CHARLES MODICA

Mr. Chairman and members of the subcommittee, I am pleased to appear before you today to speak about St. Georges University School of Medicine in Grenada to discuss the issue of federal support for students attending foreign medical institutions. I am Charles Modica, Chancellor of St. Georges University School of Medicine.

Since St. Georges was founded in August of 1976, nearly 800 students have graduated with degrees in medicine, many whom return to the United States to practice in underserved areas. Often in inner city area teaching hospitals that treat great numbers of low income and indigent patient populations, 80-90% of residency positions are filled by graduates of foreign medical schools. There would be a significant problem in handling the patient load in many of these hospitals if not for these slots being filled by eager graduates from non U.S. schools such as St. Georges.

The Journal of the American Health Association in its January 18, 1985 issue reported St. Georges University School of Medicine students were the top scorers in the U.S. qualifying examinations. This rating includes approximately 1,000 medical schools in the world. As each class at St. Georges finishes its second year of medical education, approximately one-third of that class transfers to U.S. medical schools to complete their education.

The list of hospitals, many affiliated with U.S. medical schools where most foreign trained medical graduates have current residencies or have completed their specialties and subspecialties, includes almost every state in the union. St. Georges graduates are participating in 297 different training programs in 192 hospitals. St. Georges graduates are, for the most part doing equal or better than many U.S. graduates. They are liscensed and practice in almost every state.

Mr. Chairman, I mention the above points for several reasons, but mostly to dispel the myth that all students trained at foreign medical schools are second rate. Further, I want to make it clear that the same holds true for the institutions at which these students train. In this brief exchange, I hope to set apart St. Georges University School of Medicine from other institutions that have been accused of providing less than adequate medical education.

St. Georges, and other off-shore institutions have faced an organized effort by several U.S. medical societies and organizations to diminish the credibility of their graduates and to restrict the entry of those who have completed its educational process. This organized effort includes restricting admissions to licensing examinations, refusal to issue licensing applications, restricting admissions to residency programs, and insisting on separate examinations from those given to U.S. medical students and graduates. Could a primary reason for this be that when in 1979, St Georges students who took the same examination that U.S. medical students took, scored so much higher than most U.S. students?

Mr. Chairman, recently Congress has considered several proposals to reduce or eliminate Medicare Graduate Medical Education funding for the training of students educated in foreign medical institutions. As you are most likely aware, the recently passed budget reconciliation bill requires that a foreign trained student pass the Foreign Medical Graduate Examination in the Medical Sciences (FMGEMS) to qualify for GME funding. We at St. Georges believe this is a fair compromise, and does not arbitrarily discriminate against a student based solely on his/her place of education. We applaud Congress' discretion in making this provision fair.

I come before you today to request that in your subcommittee's consideration of funding of federal programs for health professions, and student aide (particularly Guaranteed Student Loans) that you take these aforementioned statements into consideration. The Education Department has made several attempts to administratively cut off Guaranteed Student Loans to U.S. residents attending foreign medical schools. Should a proposal like this develop during your subcommittee's consideration, I am hopeful you will use the same discretion that the reconciliation conference yielded, a fair and equitable approach to the pursual of funds for all U.S. students, not withstanding their choice of U.S. or foreign schools. Further, while our students or institutions do not receive a great deal of the health professions resources allocated by your panel, we urge that you resist the overtures of select groups in organized medicine to discriminate against graduates of schools abroad, and St. Georges in particular. In the event that there are cuts suffered, I would enter a plea for equality for all U.S. medical students whether they study in the continental U.S. or are forced to study elsewhere.

Thank you for the opportunity to present our views. I am happy to respond to any questions you may have.

Senator INOUYE. Do you have any trouble with the Government now?

Mr. MODICA. No; we get along very well with the government in Grenada now, that is to say a duly elected government.

Senator INOUYE. Were you having problems before?

Mr. MODICA. Well, I think we had a few, and I think there was an intervention in between, and right now the country of Grenada is prospering a little bit more than it was before, and we are trying to play an important role in that.

Some of our graduates, in fact, have taken the place of Cuban physicians in the hospital in St. Georges.

Senator INOUYE. Thank you very much.

Mr. MODICA. Thank you.

STATEMENT OF HARRY METCALF, M.D., CHAIRMAN, BOARD OF DIRECTORS, AMERICAN ACADEMY OF FAMILY PHYSICIANS

Senator INOUYE. Our next witness is Dr. Harry Metcalf, chairman of the Board of Directors, American Academy of Family Physicians.

Doctor, welcome.

Dr. METCALF. Thank you, Mr. Chairman.

My name is Harry Metcalf. I am a practicing family physician of 25 years from Williamsville, NY, and currently serve as chairman of the Board of Directors of the American Academy of Family Physicians.

I am speaking to you today on behalf of the 57,000 members of the American academy and also the 2,400 members of the Society of Teachers of Family Medicine. We appreciate the opportunity to appear before you and to testify in support of maintaining funding for family practice training programs.

Again this year, family practice is threatened by the administration's proposed elimination of all funding to health profession education programs. The strong support of this subcommittee for these programs has enabled this specialty to remain viable in spite of dwindling economic resources. Your continued support is critical, as Congress faces increasingly difficult budget decisions. In view of the track record of family practice programs, whose success has brought primary health care to millions of Americans, your continued support is justified.

As you know, last year Congress passed a 3-year reauthorization of health professions programs. A 3-year commitment to continued support of family practice and other primary care training was made because Congress recognized the need to continue targeted Federal support. The funds for family practice have been used to establish, maintain, and improve family practice residency programs and departments of family medicine in medical schools.

We believe that the fiscal year 1987 appropriation should be the same amount called for in the Health Professions Training Assistance Act, $37 million for residency training in family practice, section 786, and $7 million for departments of family medicine, section 780. These amounts received careful congressional scrutiny during the debate on reauthorization and were determined to be adequate to sustain current training programs. Although the amounts are not large in terms of the overall budget, they have a significant impact on the ability of family practice training programs to continue to operate.

The administration's proposal, on the other hand, would ignore the will of the Congress by terminating Federal assistance to these programs, thereby jeopardizing the training of family physicians and disrupting the future delivery of primary health care in America. The administration's rationale for discontinuing this support is based on the projected national surplus of health professionals by 1990 and improved geographic distribution; however, the "Fifth Report to Congress on the Status of Health Personnel in the United States, March 1986," notes a continuing decline in the percentage of general family practitioners as a percentage of all physicians. Family physicians are not among those specialties projected to be in oversupply. In fact, with the gradual decline in family practice residency programs, we suggest that there may be a shortage of family physicians by that time.

Financial constraints such as those proposed by the administration inevitably will result in more program closures and reduction in the training of family physicians.

The fifth report also estimated that about 14 million persons remain underserved in the Nation's primary care health manpower shortage areas. As you know, family practice residency graduates locate and practice in underserved areas, both inner city and rural areas. Family practice residency programs, therefore, fulfill an essential societal need, producing well-qualified family physicians, able to provide cost effective, comprehensive, and continual care to all members of the family, regardless of age, sex, or medical condition.

Family physicians are currently providing care to a significant segment of the elderly population and will continue to do so at an increasing rate as the age of their patients increase. Geriatric health care has been and continues to be such an element in family practice training programs.

Government support for family practice programs over the past decade is largely responsible for the development and growth of this specialty, and such support is essential to maintain the progress that has been made in this patient-oriented discipline.

Why won't many of these residencies survive without direct Federal subsidy?

Family practice is a combination of ambulatory and in-hospital training, with the emphasis on ambulatory. Due to this emphasis, family practice programs incur considerable expense outside the hospital setting and are not reimbursed by Medicare or other third-party payers on a cost basis through the hospital.

In addition to higher cost, the income of family practice training programs is lower due to significant payment differentials between physicians' cognitive and procedural services, between physicians of different specialties providing similar services, and between rural and urban areas.

Facing intense budget constraints, teaching hospitals will have fewer incentives to retain family practice and other primary care training programs. The Federal grants help offset some of these disincentives.

The American Academy of Family Physicians is sensitive to the financial constraints faced by Congress. We share the concern that Federal funds be expended responsibly and that Federal resources not be used to duplicate efforts by other levels of government or the private sector. For family practice, Federal support is essential to the survival of the programs, and in view of the need for well-qualified physicians to provide comprehensive, cost-effective, ambulatory-based primary care services, we believe that continued Federal support of family practice training programs is a sound investment in the future of our Nation's health.

PREPARED STATEMENT

We respectfully request that the appropriation level for family practice programs be the same as that authorized by Congress for fiscal year 1987.

[The statement follows:]

STATEMENT OF HARRY METCALF

My name is Harry L. Metcalf, M.D. I am a practicing family physician from Williamsville, New York and currently serve as Chairman of the Board of Directors of the American Academy of Family Physicians.

The American Academy of Family Physicians appreciate the opportunity to appear before you to testify in support of maintaining funding for family practice training programs. Again, this year, family practice training is threatened by the Administration's proposed elimination of all Public Health Service funding to health professions education programs. The strong support of this subcommittee for these programs has enabled this specialty to remain viable inspite of dwindling economic resources. Your continued support of these programs is critical as Congress faces increasingly difficult budget decisions. And in view of the track record of family practice programs, whose success has brought primary health care to millions of Americans, your continued support is justified.

As you are aware, last year Congress passed a three year reauthorization of the Health Professions Training Assistance Act, P.L. 99-129, which contains funding provisions for primary care training programs under the Public Health Service Act. A three-year commitment to continued family practice and other primary care training was made because Congress recognized the need to continue targeted federal support for such training. Section 786 of the Act provides authorization levels of $36 million, $37 million and $39.4 million in FYs 1986-1988 for grants to support residency training programs in family practice, faculty development and predoctoral training programs in family medicine (with 7.5% for general dentistry). The funds authorized by Section 786 have been used to establish, to maintain and to improve family practice residency programs. These funds currently support 180 graduate projects, 62 predoctoral projects and 49 faculty development projects totalling 301. Another section of the Act, Section 780, authorizes grants to schools of medicine to establish, maintain and/or improve academic and administrative units to provide clinical instruction in family medicine. The three year authorization amount for this Section is $7 million per year. This amount currently supports 61 projects. Appropriation levels for FY 1986 were the same amounts authorized in the Act.

We believe that the FY 1987 appropriation should be the same amount called for in the Health Professions Training Assistance Act, which provides a small increase over the FY 1986 level in Section 786 and freezes Section 780 funding. These amounts received careful Congressional scrutiny during the debate on the reauthorization of the Health Professions bill and were determined to be adequate to sustain current training programs. According to the October 3, 1985 floor statement of Henry A. Waxman, Chairman of the House Energy and Commerce Subcommittee on Health and the Environment, "Funding levels in this bill are quite modest. The total authorizations are frozen at the 1985 appropriations level for 1 year. For the 2 subsequent years, funding is permitted to increase at rates of 2.7 percent and 2.3 percent, respectively, or about one-half of the level estimated by the CBO as necessary to continue current services." Although the amounts are not large in terms of the overall budget, they have a significant impact on the ability of family practice training programs to continue to operate.

The Administration's proposal, on the other hand, would ignore the will of Congress by terminating all federal assistance to these programs, thereby jeopardizing the residency training of family physicians and disrupting the future delivery of primary health care in America. The Administration's rationale for discontinuing the health professions training programs is based on a projected national surplus of health professions by 1990 and improved geographic distribution. We believe these conclusions over-generalize and are driven by efforts to cut the budget. A recent report of the Bureau of Health Professions, "Fifth Report to the President and Congress on the Status of Health Personnel in the United States (March 1986)," notes "a continuing decline in the percentage of general/family practitioners (as a proportion of all physicians)." Data compiled by the Academy indicates that the number of residents in family practice programs in July 1985 was 7,486, exactly the same number as in 1984. Since its peak in 1983, the number of accredited family practice residency programs has decreased by ten. Family physicians are not among those specialties projected to be in oversupply by 1990. Furthermore, if the decline in family practice residency programs continues, we suggest there may be a shortage of family physicians by 1990. Financial constraints, such as those proposed by the Administration, inevitably will result in more program closures and a reduction in the training of family physicians.

The Fifth Report also estimates that about 14 million persons or 6 percent of the U.S. residency population remain underserved in the Nation's primary care health manpower shortage areas. Many family practice residency graduates locate and practice in underserved areas—both inner city and rural areas. For example, among 1985 family practice residency graduates, approximately 50% entered practice in communities with populations of 25,000 or less and 70% of these communities are not within 25 miles of a large city. This compares with approximately 11% of physicians in other specialties who enter practice in non-metropolitan areas. Many of these areas seek family physicians over other specialists because of their training.

Family Physicians have been selected by the National Health Service Corps (NHSC) as uniquely qualified to perform in health manpower shortage areas. The Director of the National Health Service Corps, Kenneth Moritsugu, M.D., in explaining the NHSC preference for assigning family physicians to rural areas, has stated in a letter to the AAFP, "Family Physicians, by virture of their training, are capable of providing the full spectrum of primary care to all family members, in both urban and rural settings. They are the compleat physicians who can practice pediatrics, internal medicine, obstetrics and gynecology, general surgery and psychosocial medicine. For this reason, family physicians are the most capable specialists for the provision of primary health care in areas where complementary specialty backup may not be present. These statements cannot be made for any of the other specialties available to the NHSC, because they must rely on other specialists to provide the full complement of primary care for the family." We believe the country continues to need well-qualified family physicians who provide cost-effective, preventive care in an ambulatory setting. Family practice residency programs, therefore, fulfill an essential societal need, producing well-qualified family physicians able to provide cost-effective, comprehensive and continual care to all members of the family regardless of age, sex or medical condition.

Family physicians are currently providing care to a significant segment of the elderly population and will continue to do so at an increasing rate as the age of their patients increases. Furthermore, due to extended life expectancy, it is predicted that there will be an increased demand for services of qualified health personnel trained in geriatrics. Because family physicians are trained to treat the entire family, they are exceptionally qualified to administer to the majority of the elderly population's health care needs. Geriatric health care has been and continues to be an essential element in family practice training programs.

Congress recently passed the Consolidated Omnibus Budget Reconciliation Act, H.R. 3128, which establishes a Council on Medical Education. The Council is directed to make recommendations to the HHS Secretary and Congress regarding the current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties. This is to include appropriate federal policy concerning changes in the financing of undergraduate and graduate medical medical education programs. We believe that current proposals to reduce or terminate family practice education funding are short-sighted and ignore long-term health care policy. The Council should be allowed to make its assessment and offer its recommendations so the delivery of health care is not irrationally disrupted.

For the past decade, Congress has targeted family practice for financial support. Government support for family practice programs over the past decade is largely responsible for the development and growth of the specialty. And such government support is essential to maintain the progress that has been made in this discipline. Without direct federal support many of these family practice residencies will not survive.

Why won't they survive without direct federal subsidy? The reasons are due to the unique characteristics of family practice residencies that affect their expenses and income. Most postgraduate medical training is hospital-centered. Family practice training is a combination of ambulatory and in-hospital training, with the emphasis on ambulatory. Due to this emphasis, family practice programs incur considerable expenses outside the hospital setting which are not reimbursed by Medicare or other third party payers on a cost basis through the hospital.

In addition to higher costs, the income of family practice training programs is lower. Inherent in the Medicare program are significant payment differentials between physicians cognitive and procedural services, between physicians of different specialties providing similar services and between rural and urban areas. The existing reimbursement system discourages the type of care it should be encouraging--preventive, comprehensive, ambulatory-based care--while rewarding procedurally-oriented, inpatient, episodic care. Those skills and procedures which are taught to family practice residents, and which emphasize ambulatory care and disease prevention, contribute to better health and more cost-effective health care, but do not generate patient care revenue sufficient to underwrite graduate training in family medicine. Consequently, while traditional theory holds that approximately one-half of graduate medical education programs costs should be recovered through income from patient care services, reality shows that this is an unrealistic expectation for family practice. Current data indicate that revenues from patient care provide only 30 percent of the funding for family practice residency programs. Hospital and public dollars support the remainder. Facing intense budget constraints, teaching hospitals will have fewer incentives to retain family practice and other primary care training programs. The federal grants provided by the Public Health Service help offset some of these financial disincentives.

The American Academy of Family Physicians is sensitive to the financial constraint faced by the Congress. We share the concern of Congress that federal funds be expended responsibly and that federal resources not be used to duplicate programmatic efforts by other levels of government or by the private sector. For family practice training programs, elimination of federal support will result in elimination of programs. In view of the need for well qualified physicians to provide comprehensive, cost-effective, ambulatory based primary care services, we believe that continued federal support to family practice training programs is a sound investment in the future of our nation's health. We respectfully request the appropriation level for family practice programs be the same as that authorized for the fiscal year 1987.

Senator INOUYE. What is the effect of tort liability on your practice?

Dr. METCALF. It has probably had the most significant effect of anything else to restructure the care provided by family physicians. Especially in the rural areas, family physicians are giving up obstetrical care, which I feel is an integral part of family practice, and are forced, because of the high cost of the liability insurance, to stop providing that particular part of the medical care services that are so essential.

Senator INOUYE. Well, I can assure you that most of us support you, and every effort will be made to fund the authorized levels.

Dr. METCALF. Thank you very much.

Senator INOUYE. Thank you, doctor.

STATEMENT OF EDYTH SCHOENRICH, M.D., ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH, ASSOCIATE DEAN, SCHOOL OF HYGIENE, JOHNS HOPKINS UNIVERSITY

Senator INOUYE. Our next witness is Dr. Edyth Schoenrich, Association of Schools of Public Health.

Dr. SCHOENRICH. Senator Inouye, before I deliver my testimony on behalf of the Association of Schools of Public Health, I personally want to thank you on behalf of all my colleagues at the 23 schools for your longstanding support of academic public health programs. Senator, without your committed backing over the years, the students, the faculties, and public health service projects, supported partially by Federal funds, would have been severely impacted by the loss of Federal supports of the type about which I am testifying today.

Thank you. We are deeply appreciative of your confidence in our ability to prepare professional men and women to solve the public health problems facing our country today.

Mr. Chairman, I am Dr. Edyth Schoenrich, associate dean of the School of Public Health at the Johns Hopkins University in Baltimore. I am speaking today on behalf of the Association of Schools of Public Health, the deans of the 23 accredited U.S. schools of public health, and I appreciate the opportunity to present our testimony on the fiscal 1987 budget appropriations.

We urge the subcommittee to continue Federal institutional support to these graduate schools of public health. You have been very supportive of them over the years. In fact, congressional support for schools of public health began in 1956, making it the oldest Federal health professions education aid program in the country.

Since this Federal assistance program began, the number of accredited schools has doubled from 11 to 23, and enrollment has increased fivefold. Over 9,000 students are expected to enroll this September.

Yet, Mr. Chairman, there are still definite shortages of public health professionals today. According to the Department of Health and Human Services, there are insufficient public health personnel prepared to cope with all the demands to be placed upon them in the coming decades. Nationally, there appears to be a critical shortage of epidemiologists and biostatisticians, professionals who use quantitative techniques to define disease problems in communities, the factors which make people at risk for these diseases, the clues to the causes of these diseases, and the evaluation of interventions designed to control or prevent these diseases.

The lack of environmental health specialists, the lack of noninfectious disease and behavioral epidemiologists, public health nurses, toxicologists, risk assessment specialists in the chemical and physical agent areas, and health care finance specialists are most often cited by the Department of Health and Human Services.

A severe shortage of physicians exists throughout the field of public health. In epidemiology, the lack of physicians is particularly acute, but it is also anticipated that there will be a strong demand for nonphysician epidemiologists with doctoral training as long as this shortage exists.

In environmental health, areas related to toxic substances, hazardous waste management, occupational safety and health, environmental epidemiology, and water treatment will experience the greatest shortage of adequately trained personnel to meet the needs of both public and private sectors.

In health administration, specialists in finance and economics will continue in high demand. And especially relevant within the last 2 weeks are specialists in radiation health problems, both due to acute exposure and to chronic low-grade exposure.

There is also a pressing need for improving the abilities and skills of those already in the public health work force. For example, according to Health and Human Services, one-half of the environmental work force has not been formally prepared in either the health or environmental sciences, in part because of the extraordinarily rapid technological changes.

Schools of public health have experienced decreasing trends in the number of physicians attending and entering academic public health. The dearth of professional staff in the field of public health and preventive medicine has been documented in report after report, ranging from studies by the Graduate Medical Education National Advisory Committee to those of the National Academy of Sciences.

Mr. Chairman, I have attached to our testimony a document outlining the shortages in greater detail, which with your permission, I would like to add to the record.

Senator INOUYE. Without objection, so ordered.

Dr. SCHOENRICH. Thank you.

Given the shortfall in public health professionals, the administration proposes this year to end academic public health capitation, traineeships, and support for preventive medicine residency projects, as well as support for the Center for Disease Control prevention centers and the Administration on Aging's health promotion projects by requesting no funds for these programs in fiscal 1987.

Since there is a short supply of Public Health Service personnel in our Nation, and preventing diseases is more cost effective than curing them, it is surprising for the administration to propose ending Federal support to schools of public health.

Given the present state of the deficit, certain reductions in Federal spending are justified. I, too, am a taxpayer and have an investment in a stable economy. However, to recommend cuts in programs that contribute to keeping individuals out of the costly medical care system does not seem rational. Cost savings in the health care system can be achieved through greater emphasis, not through reductions on programs that keep people and communities healthy.

Based on the fact that public health personnel shortages exist, we believe that continued Federal support is justified. Federal support is also justified on the grounds that graduates of the schools of public health work primarily in the public sector in the areas of health of promotion and disease prevention, and unlike graduates of other schools in the health professions, do not enjoy lucrative incomes. The mean annual income of 1981 graduates was $24,500.

These people represent the basic resource pool from which Federal, State, and local health and environmental agencies draw their manpower needs. Graduates also work and teach in university settings, and industry in the private sector relies heavily on these schools to train their employees involved in industrial hygiene and occupational safety and health.

Finally, Mr. Chairman, Federal support is justified because these schools of public health train professionals that will prevent disease and promote health. I have attached a letter from our president, Dr. William Bridgers, to you that highlights some of the major contributions of the schools of public health to disease prevention in this country.

PREPARED STATEMENT

Thank you for allowing us the opportunity to present our views. We respectfully urge that Congress approve our request for the Public Health Service programs of primary concern to the schools of public health and, I would add, to the Nation. I know you are very familiar with many of these facts, but if you have any questions, I'd be very pleased to answer them.

[The statement follows:]

Statement of Edyth Schoenrich

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, I AM DR. EDYTH SCHOENRICH, ASSOCIATE DEAN OF THE SCHOOL OF HYGIENE AND PUBLIC HEALTH OF THE JOHNS HOPKINS UNIVERSITY. I AM SPEAKING TODAY ON BEHALF OF THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH. THE DEANS OF THE 23 U.S. SCHOOLS OF PUBLIC HEALTH APPRECIATE THE OPPORTUNITY TO PRESENT OUR TESTIMONY ON FY87 APPROPRIATIONS.

WE URGE THE SUBCOMMITTEE TO CONTINUE FEDERAL INSTITUTIONAL SUPPORT TO THESE GRADUATE SCHOOLS OF PUBLIC HEALTH. YOU HAVE BEEN VERY SUPPORTIVE OF THEM OVER THE YEARS. IN FACT, CONGRESSIONAL SUPPORT FOR SCHOOLS OF PUBLIC HEALTH BEGAN IN 1956, MAKING IT THE OLDEST FEDERAL HEALTH PROFESSIONS EDUCATION AID PROGRAM IN THE COUNTRY. SINCE THIS FEDERAL ASSISTANCE PROGRAM BEGAN, THE NUMBER OF ACCREDITED SCHOOLS HAS DOUBLED FROM 11 TO 23 AND ENROLLMENT HAS INCREASED FIVEFOLD (OVER 9,000 STUDENTS ARE EXPECTED TO ENROLL THIS SEPTEMBER). YET, MR. CHAIRMAN, THERE ARE STILL DEFINITE SHORTAGES OF PUBLIC HEALTH PROFESSIONALS TODAY. ACCORDING TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, THERE ARE INSUFFICIENT PUBLIC HEALTH PERSONNEL PREPARED TO COPE WITH ALL THE DEMANDS TO BE PLACED ON THEM IN THE COMING DECADE. NATIONALLY, THERE APPEARS TO BE CRITICAL SHORTAGE OF EPIDEMIOLOGISTS, HEALTH STATISTICIANS, AND CERTAIN TYPES OF ENVIRONMENTAL HEALTH SPECIALISTS. THE LACK OF NON-INFECTIOUS DISEASES AND BEHAVIORAL EPIDEMIOLOGISTS, PUBLIC HEALTH NURSES, TOXICOLOGISTS, RISK ASSESSMENT SPECIALISTS IN THE CHEMICAL AND PHYSICAL AGENT ARENAS, HEALTH CARE FINANCE SPECIALISTS, AND BIOSTATSTICIANS ARE MOST OFTEN CITED BY HHS.

A SEVERE SHORTAGE OF PHYSICIANS EXISTS THROUGHOUT THE FIELD OF PUBLIC HEALTH. IN EPIDEMIOLOGY, A LACK OF PHYSICIANS IS PARTICULARLY UTE, AND IT IS ANTICIPATED THAT STRONG DEMAND FOR NONPHYSICIAN EPIDEMIOLOGISTS WITH DOCTORAL TRAINING WILL CONTINUE AS LONG AS THIS SHORTAGE EXISTS. IN ENVIRONMENTAL HEALTH, AREAS RELATED TO TOXIC SUBSTANCES, HAZARDOUS WASTE MANAGEMENT, OCCUPATIONAL SAFETY AND HEALTH, ENVIRONMENTAL EPIDEMIOLOGY, AND WATER TREATMENT WILL EXPERIENCE THE GREATEST SHORTAGE OF ADEQUATELY TRAINED PERSONNEL TO MEET THE NEEDS OF BOTH PUBLIC AND PRIVATE SECTORS. IN HEALTH ADMIN-

ISTRATION, SPECIALISTS IN FINANCE AND ECONOMICS WILL CONTINUE IN HIGH DEMAND.

IN OTHER FIELDS, PUBLIC HEALTH PERSONNEL GROWTH WILL BE SLOW TO MINIMAL. IN THE SLOW GROWTH DISCIPLINES, THE MOST PRESSING NEEDS ARE FOR IMPROVING THE ABILITIES AND SKILLS OF THOSE ALREADY IN THE WORK FORCE. ACCORDING TO HSS, HALF OF THE ENVIRONMENTAL HEALTH WORKFORCE HAS NOT BEEN FORMALLY PREPARED IN EITHER THE HEALTH OR ENVIRONMENTAL SCIENCES.

SCHOOLS OF PUBLIC HEALTH ARE CURRENTLY EXPERIENCING ANOTHER MAJOR CRISIS CAUSED BY A DECREASING TREND IN THE NUMBER OF PHYSICIANS ENTERING ACADEMIC PUBLIC HEALTH. THE DEARTH OF PROFESSIONAL STAFF IN THE FIELD OF PUBLIC HEALTH AND PREVENTIVE MEDICINE HAS BEEN DOCUMENTED IN REPORT AFTER REPORT RANGING FROM STUDIES BY THE GRADUATE MEDICAL EDUCATION NATIONAL ADVISORY COMMITTEE TO THOSE OF THE NATIONAL ACADEMY OF SCIENCES. IN NOTABLE CRITICAL SUPPLY ARE PHYSICIANS TRAINED IN PREVENTIVE MEDICINE, EPIDEMIOLOGY, BIOSTATISTICS, AND TOXICOLOGY.

MR. CHAIRMAN, I'VE ATTACHED TO OUR TESTIMONY A DOCUMENT OUTLINING THESE SHORTAGES IN GREATER DETAIL.

GIVEN THIS SHORT-FALL IN PUBLIC HEALTH PROFESSIONALS, THE ADMINISTRATION PROPOSES TO END THIS YEAR ACADEMIC PUBLIC HEALTH CAPITATION, TRAINEESHIPS AND SUPPORT FOR PREVENTIVE MEDICINE RESIDENCIES, AS WELL AS SUPPORT FOR CDC'S PREVENTION CENTERS AND AoA'S HEALTH PROMOTION PROJECTS, BY REQUESTING THE RECISSION OF FY86 FUNDS AND REQUESTING NO FUNDS FOR THESE PROGRAMS IN FY87.

SINCE THERE IS A SHORT SUPPLY OF PUBLIC HEALTH PERSONNEL IN OUR NATION AND PREVENTING DISEASE IS MORE COST EFFECTIVE THAN CURING IT, IT IS SURPRISING AND CONFUSING FOR THE ADMINISTRATION TO PROPOSE ENDING FEDERAL SUPPORT TO SCHOOLS OF PUBLIC HEALTH. GIVEN THE PRESENT STATE OF THE DEFICIT, CERTAIN REDUCTIONS IN FEDERAL SPENDING ARE JUSTIFIED. HOWEVER, TO RECOMMEND CUTS IN PROGRAMS THAT CONTRIBUTE TO KEEPING INDIVIDUALS OUT OF THE COSTLY MEDICAL CARE SYSTEM DOES NOT MAKE SENSE. COST SAVINGS IN THE HEALTH CARE SYSTEM CAN BE ACHIEVED THROUGH GREATER EMPHASIS (NOT REDUCTIONS) ON PROGRAMS THAT KEEP PEOPLE AND COMMUNITIES HEALTHY.

BASED ON THE FACT THAT PUBLIC HEALTH PERSONNEL SHROTAGES EXIST, WE BELIEVE THAT CONTINUED FEDERAL SUPPORT IS JUSTIFIED. FEDERAL SUPPORT IS ALSO JUSTIFIED ON THE GROUNDS THAT GRADUATES OF THE SCHOOLS OF PUBLIC HEALTH WORK PRIMARILY IN THE PUBLIC SECTOR IN THE AREAS OF HEALTH PROMOTION AND DISEASE PREVENTION AND, UNLIKE GRADUATES OF OTHER SCHOOLS OF THE HEALTH PROFESSIONS, DO NOT ENJOY LUCRATIVE INCOMES (MEAN INCOME OF 1981 GRADUATES WAS 24,500). THEY REPRESENT THE BASIC RESOURCE POOL FROM WHICH FEDERAL, STATE AND LOCAL HEALTH AND ENVIRONMENTAL AGENCIES DRAW THEIR MANPOWER NEEDS. GRADUATES ALSO WORK AND TEACH IN UNIVERSITY SETTINGS AND INDUSTRY RELIES HEAVILY ON THE SCHOOLS TO TRAIN THEIR EMPLOYEES INVOLVED IN INDUSTRIAL HYGIENE AND OCCUPATIONAL SAFETY AND HEALTH.

FINALLY, MR. CHAIRMAN, FEDERAL SUPPORT IS JUSTIFIED BECAUSE THESE SCHOOLS OF PUBLIC HEALTH TRAIN PROFESSIONALS THAT WILL PREVENT DISEASE AND PROMOTE HEALTH. I'VE ATTACHED A LETTER FROM OUR PRESIDENT, DR. WILLIAM BRIDGERS, TO YOU THAT HIGHLIGHTS SOME OF THE MAJOR CONTRIBUTIONS OF THE SCHOOLS OF PUBLIC HEALTH TO DISEASE PREVENTION IN THIS COUNTRY.

THANK YOU, MR. CHAIRMAN, FOR ALLOWING US THE OPPORTUNITY TO PRESENT OUR VIEWS. WE RESPECTFULLY URGE THAT CONGRESS APPROVE OUR REQUESTS FOR PHS PROGRAMS OF PRIMARY CONCERN TO THE SCHOOLS OF PUBLIC HEALTH. THANK YOU.

The Association of Schools of Public Health (ASPH) urges Congress to disapprove the Administration's request to rescind FY86 funds to Schools of Public Health and to approve the following amounts for FY87:

APPROPRIATIONS (Millions)

	Final FY 1983	Final FY 1984	Final FY 1985	Final* FY 1986	Pres. FY1987 Requests	FY87 Author	ASPH Request FY87**
Institutional Support (Capitation)	$4.1	$5.0	$5.0	$5.0	0	$5.0	$5.0
Traineeships	$2.5	$2.5	$3.0	$3.0	0	$3.0	$3.0
Preventive Medicine Residencies	$1.0	$1.5	$1.6	$1.6	0	$1.6	$1.0
Centers for Health Promotion and Disease Prevention (CDC)	--	--	--	$1.5	0	$13.0	$5.0
Older Americans Health Promotion and Disease Prevention Projects (Title VII)	--	--	--	$1.0	0	$8.5	$3.0
Educational Resource Centers (NIOSH)	$5.7	$8.7	$8.7	$8.7	0	N/A	$8.3

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* The Administration is proposing to rescind these funds this year.
** Figures take into account Gramm-Rudman reductions.

PUBLIC HEALTH MANPOWER SHORTAGES:
Personnel in Short Supply

The Federal Government's responsibilities and objectives in the field of health promotion and disease prevention warrant a continued high level of concern for manpower resources in public health. Adequately trained public health professionals, effectively utilized, are essential to progress in prevention of diseases and the identification and control of environmental health hazards, among other national priority health goals. Again, health professions schools can be expected to initiate or expand programs aimed at addressing these critical health needs.

Types of specialists for which need continues to exist include:

- epidemiologists knowledgeable about non-infectious disease, new-generation infectious disease, and environmental problems;
- environmental health professionals skilled in toxicology, assessment of risks related to hazardous chemical and physical agents, and other specialty areas;

- public health nurses, nutritionists, and health educators prepared to address problems of children, the aged and the disadvantaged.

-- Robert Graham, M.D.
Administrator
Health Resources and
Services Administration
HHS
Testimony before the
House Subcommittee on
Health and the
Environment
April 24, 1984*

The President's justification for requesting FY86 rescissions and FY87 termination of funds to support Schools of Public Health is based on a series of false assumptions. First, federal health professions education policy has focused almost exclusively on hands-on physicians and their supply and OMB has based policy decisions affecting *other* health professionals on conclusions relating to these physicians. For example, HHS studies have shown that there will be an oversupply of physicians around 1990. Based on is finding, the President zeros-out support for public health professionals that are undersupply. Available evidence indicates an *undersupply* of public health personnel exists.

In 1979, the Surgeon General released his report, *Healthy People*, which said that although there is a lack of hard public health manpower data, there are definite shortages of certain specialized disciplines such as epidemiologists, biostatisticians, occupational and environmental health workers and health services administrators and managers. The majority of these professionals in great demand are trained in the 23 graduate U.S. *Schools of Public Health*.** The reasons for the lack of data are several, such as the lack of uniform and fixed definitions of public health jobs and equirements for employment, methodological problems and high costs of gathering information.

A December 1979 HHS report to Congress on community and public health personnel also called for increased federal support to rograms training professionals in these priority public health areas. Furthermore, both the Institute of Medicine ("A Manpower Policy for Primary Care") and the HHS Graduate Medical Educational National Advisory Committee (report of September 1980) made a number of recommendations relating to increased federal support for public health and preventative medicine training programs because there are definite shortages in these specialized fields. (See Attachment A).

Both the 1980 and 1982 HHS reports to Congress on health professions reported that there are shortages of qualified public health professionals, especially environmental health specialists (toxicologists), epidemiologists, biostatisticians, public health physicians and nurses, among others. A 1980 HHS study of nutrition personnel in state health agencies reported significant vacancy slots for nutritionists.

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*Same observations were made by Edward Brandt, M.D., Assistant Secretary for Health, HHS, before the Senate Committee on Labor and Human Resources, March 14, 1984.

** University of Alabama at Birmingham, Boston University, University of California-Berkeley, UCLA, Columbia University, Harvard University, University of Hawaii, University of Illinois at Chicago, Johns Hopkins University, Loma Linda University, University of Massachusetts, University of Michigan, University of Minnesota, University of North Carolina, University of Oklahoma, University of Pittsburgh, University of Puerto Rico, San Diego State University, University of South Carolina, University of South Florida, University of Texas, Tulane University, University of Washington, Yale University.

The HHS Bureau of Health Professions (BHPr) reports that there is a shortage of faculty and researchers with expertise in a number of high-priority subject areas including chronic-disease, behavioral, d environmental epidemiology and environmental toxicology, including risk assessment of chemical and physical agents. Also in short supply among university faculties are public health nutritionists, occupational health specialists, and analytical scientists such as mathematical statisticians, biostatisticians, and computer specialists.

A 1985 BHPr draft report to Congress states that there exists a severe shortage of physicians throughout the field of public health. In epidemiology, a lack of physicians is particularly acute, and it is anticipated that a strong demand for nonphysician epidemiologists with doctoral training will continue as long as this shortage exists. In environmental health, areas related to toxic substances, hazardous waste management, occupational safety and health, environmental epidemiology, and water treatment will experience the greatest shortage of adequately trained personnel to meet the needs of both public and private sectors. In health administration, specialists in finance and economics will continue in high demand.

Schools of public health are currently experiencing another major crisis caused by a decreasing trend in the number of physicians ering academic public health. The dearth of professional staff in the field of public health and preventive medicine has been documented in report after report ranging from studies by the graduate medical education national advisory committee to those of he national academy of sciences. In notable critical supply are physician educators trained in preventive medicine, epidemiology, biostatistics, and toxicology.

In addition, the inability of Schools of Public Health to fectively compete with the corporate arena for the modest supply of non-physician graduates in environmental toxicology, non-infectious disease and behavioral epidemiology and health care finance, creates serious problems for the Schools (and federal, state and local health agencies) in their efforts to meet present public health problems. This brain drain will accelerate as more and more environmental hazards are being brought to the public's attention.

Furthermore, many health science students are not choosing careers in public health because of the 60 percent cutback in traineeships since 1981 and the high costs of taking out HEAL loans. Physicians, engineers, nurses, chemists and physical scientists are not entering the field in adequate numbers. In engineering, the small but continuous flow of engineering graduates that entered public health through the mid-1970's has all but ceased. In veterinary medicine, recruitment of veterinarians into public health has decreased. While graduates training in many specialty areas of nursing has grown dramatically over the past 10 years, the increase in nurses trained in public health at the graduate level has not kept pace. In fact, state health officers are very alarmed about the low nber of nurses entering public health.

Given these shortages, the Administration proposes to end this year academic public health capitation, traineeships and preventive medicine residencies, as well as support for CDC's Prevention Centers and AoA's health promotion projects, by requesting the rescission of FY86 funds and requesting no funds for these programs in FY87.

Since there is a short supply of public health personnel in our nation and preventing disease is more cost effective than curing it, it is surprising and confusing for the Administration to propose ending federal support to Schools of Public Health. Given the present state of the deficit, certain reductions in federal spending are justified. However, to recommend cuts in programs that contribute to keeping individuals out of the costly medical care system does not make sense. Cost savings in the health care system can be achieved through greater emphasis (not reductions) on programs that keep people and communities healthy.

Based on the above findings and observations, ASPH believes that continued federal support is justified. (See Attachment "B".) Federal support is also justified on the grounds that graduates of the Schools of Public Health work primarily in the public sector in the areas of health promotion and disease prevention and, unlike graduates of other schools of the health professions, do not enjoy lucrative incomes (mean income of 1981 graduates was $24,500). They represent the basic resource pool from which federal, state and local health and environmental agencies draw their manpower needs. Graduates also work and teach in university settings. Industry relies heavily on the Schools to train their employees involved in industrial hygiene, occupational safety and health, environmental toxicology, among others. The breakdown is as follows: 44 percent of graduates in a single given year go into federal, state or local government service, 30 percent work for either non-profit community health agencies or universities and 22 percent work in the propietary sector.

Finally, federal support is needed to help the Schools in their efforts to train professionals that will prevent disease and promote health. The Surgeon General of the United States recently said "Further improvements in the health of the American people can and will be achieved--not through increased medical care and greater health expenditures--but through a renewed national commitment to efforts designed to prevent disease and to promote health" (Healthy People).

The Nation's Schools of Public Health

Schools of Public Health have been educating professionals in the techniques of health preservation and disease prevention and control since the early decades of the twentieth century. Some Schools of Public Health had their beginnings in university schools of medicine; others were conceived from the outset as autonomous units within their parent institutions. There are twenty-three accredited Schools of Public Health in the United States - eight at private and fifteen at public universities.

The Schools are located in seventeen states and Puerto Rico and train students from every state in the nation. With a faculty of over 2,000, graduate education is offered to a combined enrollment of approximately 9,000 students in such specialized areas as biostatistics, epidemiology, environmental and occupational health, health administration, health planning, nutrition, maternal and child health and social behavioral sciences, among others.

Attachment "A"

1990 REQUIREMENTS FOR PUBLIC HEALTH AND PREVENTIVE MEDICINE

Manpower estimated by GMENAC

On September 23, 1980, the HHS Graduate Medical Education National Advisory Committee (GMENAC) met in Washington and adopted final recommendations (shown below) regarding the needed number of public health physicians for each specialty for 1990.

Present Supply	Aerospace Medicine	Occupational Medicine	Public Health and General Preventive Medicine	Total
Board-certified(1)	783	794	2,317	3,894
Self-identified(2)				
Administration	165	541	1,555	2,291
Research	27	28	201	256
Teaching	7	9	115	131
Patient Care	368	(1,695)*	(1,048)*	368
Other	17	78	147	242
	584	656	2,048	3,288

1990 Requirements for Board-Qualified Full Time Equivalents (3)				
Program Activities	250	1,400	2,100	3,750
Research	150	200	[illegible]00	750
Teaching	60	300	450	810
Clinical Services	500	400**	400**	1,300
Other	0	0	200	200
	960	2,300	3,550	6,810

The estimate of total requirements as calculated above is 6,800-7,800.

Shortage				
Number	376	1,644	1,502	3,522
Percent	64	251	73	107

*These are felt to be physicians providing regular clinical services though in a preventive medicine setting. The 2700 physicians have not been included in the final figures because in the GMENAC methodology these physicians have been included in the enumeration of generalist physicians.

**These are in addition to other physician specialists working in a preventive medicine setting but who are providing regular clinical services.

April 23, 1986

The Honorable Mark O. Hatfield
Chairman
Subcommittee on Labor/HHS/Education
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Once again I am honored to ask for your continued support of academic public health programs, in general and for the 23 U.S. Schools of Public Health, in particular. The $25 million annual contribution by Congress is a small but fair share of the costs incurred by our 23 Schools to train over 9,000 graduate students each year (it costs approximately $10,000 per year to train one student). We feel that this support is justified because it helps Schools of Public Health train health professionals in critical supply such as epidemiologists, biostatisticians, public health nurses, toxicologists, among others, and that they contribute greatly to keeping people well and out of the costly medical care system.

The latter causes us to have an image problem, Mr. Chairman. I suspect that part of the problem for public health and for those engaged in academic pursuits of ways to prevent disease is that, if we're successful, frankly nothing much happens. It's boring to prevent, but exciting to intervene with high tech treatments. In public health we continually face a public that wants to know, "So what have you done for us lately?"

Mr. Chairman, let me describe to you what we have done and about the great contributions of faculty in the Schools of Public Health:

- Schools of Public Health have played a critical role in the complete eradication (for the only time in recorded history) of a major scourge: smallpox. The theoretical and practical capability is now at hand to replicate this feat for measles and poliomyelitis, given the resources and commitment required. Schools of Public Health are now playing a key role in urging that this be done.

- The mention of polio brings to mind that it was in a School of Public Health that the iron lung was developed, permitting many with the bulbar form of this terrible disease to be kept alive. Fortunately, the need for them was negated by the development of an effective means to protect children from this disease, and the lion's share of the critical discoveries paving the way for development of a vaccine were made in a School of Public Health.

- Going back nearer their beginnings, in the 1920's vitamin D was discovered in a School of Public Health, and it can be fairly stated that America was taught to be milk drinkers by these faculty. The general principles of nutritional (vitamin) deficiencies and their corrections by properly balanced diets can be traced to these early efforts. As a result, vitamin deficiency diseases today are rare to nonexistent in developed countries. Schools of Public Health remain hot spots for nutrition research, an area of inquiry still struggling for its place in the sun in schools of medicine.

- In the same early period the applications of statistical methods as analytical tools in the management of diseases in population was brought to maturity by faculty in a School of Public Health. Epidemiology also began its maturation then. These techniques apply not only to epidemics of infectious disease but are just as valuable and necessary for establishing, for example, the fact that seat belts save lives.

- The roles of Schools of Public Health in eradication of hookworm and other such infections and in devising strategies to deal with sexually transmitted diseases are wellknown. A more recent example is AIDS, where one of the acknowledged world-wide spokespersons addressing this new viral disease is a dean of a School of Public Health. Because an enlightened and compassionate public is presently the only means whereby the transmission of HTLV-III virus can be slowed, many Schools have begun to mount efforts to inform a nervous public about this, the most frightening threat to the public's health since the polio epidemics.

- Not as widely recognized is the pioneering work many years ago in a School of Public Health in establishing the field of industrial hygiene. Thousands of factory workers throughout the world literally owe their lives to this discipline and to the work of these professionals. The work of Schools of Public Health on water quality, hazardous waste, and air pollution has been at the cutting edge of newly recognized health hazards.

- Insights into how to prevent typhus, trachoma, malaria, and numerous other diseases prevalent in tropical regions have been an especially fruitful area of research within Schools of Public Health, with a large potential payoff in terms of improved health and socioeconomic status.

- One final excellent example of the power of the modern epidemiologic approach for understanding how to prevent disease will perhaps make an important point that the traditional medical school faculty often overlooks. I refer to the "cause" of lung cancer. Whereas the molecular basis for cancer still eludes the basic scientist, that cigarettes cause lung cancer has been just as firmly established through epidemiologic techniques as would be the case if the cause had been discovered in a test tube. That, indeed, is the message; while vitally important basic biomedical investigations into causes of diseases go forward and are to be encouraged, the applied methods of public health are of inestimable value in control and prevention of disease -- chronic, debilitating disease of modern man as well as infectious disease in developing regions of the world. In many cases, the preferred strategy for control is prevention, not treatment. Lung cancer is a case in point: there's no silver bullet for its treatment.

Based on the above findings and observations, we believe, Mr. Chairman, that continued federal support to Schools of Public Health is justified. I respectfully urge you and your colleagues to disapprove the Administration's request to rescind FY86 funds to Schools of Public Health and to approve the following amounts for FY87:

The Association of Schools of Public Health (ASPH) urges Congress to disapprove the Administration's request to rescind FY86 funds to Schools of Public Health and to approve the following amounts for FY87:

APPROPRIATIONS (Millions)

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Preventive Medicine Residencies	$1.0	$1.5	$1.6	$1.6	0	$1.6	$1.0
Centers for Health Promotion and Disease Prevention (CDC)	--	--	--	$1.5	0	$13.0	$5.0
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Educational Resource Centers (NIOSH)	$5.7	$8.7	$8.7	$8.7	0	N/A	$8.3

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* The Administration is proposing to rescind these funds this year.

** Figures take into account Gramm-Rudman reductions.

Senator INOUYE. First of all, I thank you for your generous words, but I think Dr. Jerry Michael deserves all of them.

Dr. SCHOENRICH. He's a good friend of mine, sir. And we are training his niece, by the way, at our school right now.

Senator INOUYE. Not in Hawaii?

Dr. SCHOENRICH. No; she's at our school and very happy there.

Senator INOUYE. What percentage of public health physician graduates enter into private practice?

Dr. SCHOENRICH. Very, very few enter into private practice in the sense of a clinically trained physician entering private practice in clinical medicine, opening an office, putting out a sign, and receiving patients one by one. Very few of our preventive medicine physicians do that.

Senator INOUYE. In other words, most——

Dr. SCHOENRICH. They work in organizational settings.

Senator INOUYE. Either in corporate settings or, I think, mostly Government out there.

Dr. SCHOENRICH. Yes; I have some figures on that, as a matter of fact.

Senator INOUYE. So they're not profit-motivated.

Dr. SCHOENRICH. Well, no. As a matter of fact, I've worked with students in schools of public health now for 10 or 15 years, and they are a very special group. They come really deeply committed, with a sense of mission.

Now I'm a physician myself, and I spent some 18 years in clinical medicine, and I know my colleagues, most of them at least, came with a sense of mission as well, but it's a sense of mission with different reward systems, quite different reward systems.

Senator INOUYE. Well, I thank you very much.

Dr. SCHOENRICH. All right. Thank you, sir.

STATEMENT OF F. LYNN MAY, EXECUTIVE DIRECTOR, AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

Senator INOUYE. Our next witness, F. Lynn May, executive director of the American Academy of Physicians Assistants.

Mr. MAY. Good morning, Mr. Chairman.

On behalf of the 10,000 members of the American Academy of Physician Assistants, I would like to thank you for the opportunity to testify here today and also for your support on many issues over the past years.

Last year when I spoke to you, we were not only seeking appropriations; we were also seeking authorization for physician assistants program funding, and thanks to the Congress, we received it. But that now seems somewhat of a hollow victory. Because of the effects of Gramm-Rudman, that $4.8 million has been reduced to $4.3 million, and if the administration has its way, it will be totally reduced to nothing.

Now we have been working very hard to help the physician assistants training programs to be less dependent on Federal dollars, and we've had some success in that. I think if program funding were cut substantially, most of the programs would continue to remain in existence and provide training programs. However, it would do so at a cost.

One of the things that would occur would be that tuition would be raised as a result, and while they would seek additional funding from the States, that is becoming more and more difficult as States are facing economic problems, either in the Midwest because of reduction of the agricultural economy or in the Southwest because of the lower price of oil. So if tuition goes up, the effect is going to be that indebtedness of physician assistants who go through training will grow. They will be less and less likely to go into providing care in underserved areas, and we have a proud record of providing care in those areas. Fully one-third of all physician assistants provide care in either rural or inner city areas. That's a record that exceeds many other practitioners. If their indebtedness through tuition goes up, they'll be less likely to do that.

Second, we have got a concerted effort to try to recruit minorities into the physician assistant ranks, and if tuition goes up, that's going to be more and more difficult. And so that means that they will not be able to provide the care which they tend to do toward minorities.

For those few programs that are lucky enough to get funding in the years ahead, the Congress has put all kinds of requirements on them. They must now provide rotations in home health care, in geriatrics, and in health promotion and disease prevention, which means they are going to have to do more with less. So we think that's a difficult situation for them to try to do.

So we desperately urge, Mr. Chairman, that the committee restore the funding to the level that it has for the last couple of years, and we thank you very much for the opportunity to appear before you today.

PREPARED STATEMENT

Senator INOUYE. Thank you very much. We'll do our best, sir.

Mr. May. Thank you, sir.

[The statement follows:]

Statement of F. Lynn May

MR. CHAIRMAN, ON BEHALF OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS, I WANT TO THANK YOU FOR THIS OPPORTUNITY TO TESTIFY ON THE LABOR-HHS-EDUCATION APPROPRIATION BILL FOR FISCAL YEAR 1987.

MR. CHAIRMAN, WHEN I APPEARED BEFORE YOUR COMMITTEE LAST YEAR, THE CONGRESS HAD NOT REAUTHORIZED FUNDING FOR PHYSICIAN ASSISTANT PROGRAMS. I AM PLEASED TO BE ABLE TO COME BEFORE YOU THIS YEAR WITH THE REAUTHORIZATION COMPLETE. IT IS NOT CLEAR, HOWEVER, THAT THE VICTORY LAST FALL IS REALLY WORTH MUCH.

SUBSEQUENT TO THE ENACTMENT OF PL 99-129, THE GRAMM-RUDMAN-HOLLINGS BUDGET REDUCTIONS TOOK EFFECT. THUS, EVEN THOUGH CONGRESS AUTHORIZED AND APPROPRIATED $4.8 MILLION DOLLARS FOR PHYSICIAN ASSISTANT EDUCATION, ONLY $4.3 MILLION IS AVAILABLE. THIS MEANS, MR. CHAIRMAN, THAT SOME PA PROGRAMS THAT HAD BEEN COUNTING ON FEDERAL ASSISTANCE WILL NOT BE RECEIVING ANY FEDERAL FUNDS IN FY 1986.

THE TRAGEDY OF THIS TURN OF EVENTS IS NOT GOING TO BE READILY NOTICEABLE. I FEEL CONFIDENT THAT MOST PROGRAMS THAT LOST OUT ON FEDERAL FUNDS WILL CONTINUE TO EXIST AND TURN OUT FIRST CLASS PHYSICIAN ASSISTANTS. NO, MR. CHAIRMAN, THE IMPACT OF GRAMM-RUDMAN-HOLLINGS WILL NOT TRULY BE FELT FOR A FEW YEARS, WHEN FUTURE PHYSICIAN ASSISTANT PROGRAM GRADUATES MAKE THE DECISION ON WHAT TYPE OF MEDICINE TO PURSUE.

YOU SEE, MR. CHAIRMAN, THE FUNDS THE FEDERAL GOVERNMENT MAKES AVAILABLE TO PA PROGRAMS GO, IN LARGE PART, TO

REDUCING THE COST OF EDUCATION. BY REDUCING OR ELIMINATING FEDERAL ASSISTANCE, YOU PUT INCREASING PRESSURE ON PROGRAMS TO REPLACE THOSE LOST FEDERAL FUNDS THROUGH INCREASED TUITION.

THE REDUCTION OF FUNDS AT THE FEDERAL LEVEL IS BEING EXACERBATED AT THE STATE LEVEL BECAUSE OF INCREASING BUDGETARY PRESSURES ON STATE LEGISLATURES. TWO STATES PROVIDE A GOOD EXAMPLE OF WHAT IS HAPPENING.

AS YOU KNOW, TEXAS AND NEBRASKA BOTH HAVE OUTSTANDING PA PROGRAMS. THESE PROGRAMS RECEIVE A CONSIDERABLE AMOUNT OF MONEY FROM THEIR RESPECTIVE STATE LEGISLATURES. DUE TO THE PROBLEMS IN BOTH THE FARM AND OIL INDUSTRY, IT IS APPARENT THAT THE STATES WILL NOT BE ABLE TO PROVIDE AS MUCH MONEY FOR EDUCATION AS THEY HAVE IN THE PAST.

NOW EVEN THOUGH SOME MAY CONSIDER THIS A 'CYCLICAL' PROBLEM, IT IS SYMPTOMATIC OF WHAT CAN HAPPEN TO EDUCATION AT THE STATE LEVEL. THUS, WHEN YOU COMBINE CUTBACKS AT THE FEDERAL LEVEL WITH CUTBACKS AT THE STATE LEVEL, YOU CAN SEE THAT SERIOUS PROBLEMS COULD EXIST.

THE ADMINISTRATION HAS SUGGESTED THAT THE FEDERAL GOVERNMENT SHOULD GET OUT OF THE BUSINESS OF FUNDING PA EDUCATION. AND, TO A CERTAIN DEGREE, IT IS TRUE THAT MOST PROGRAMS DO NOT NEED FEDERAL FUNDS TO SURVIVE. WHILE THE LOSS WILL BE FELT AT THE PROGRAM LEVEL, THE GREATEST IMPACT WILL BE AT THE PATIENT CARE LEVEL.

EMPLOYMENT DECISIONS

AS YOU KNOW, PAs ARE GENERALLY NOT ELIGIBLE FOR MOST FEDERAL HIGHER EDUCATION ASSISTANCE PROGRAMS. THIS MEANS THAT THE $4.8 MILLION DOLLARS AUTHORIZED FOR PA PROGRAMS IS THE MAIN SOURCE OF MONEY AVAILABLE TO REDUCE THE COST OF PA EDUCATION TO THE STUDENT. REDUCTIONS IN FEDERAL ASSISTANCE WILL INEVITABLY LEAD TO HIGHER TUITION.

PA STUDENTS, LIKE MANY OTHER YOUNG PEOPLE PURSUING A CAREER IN A MEDICAL PROFESSION, FIND IT NECESSARY TO BORROW MONEY TO PAY FOR THEIR EDUCATION. HIGHER TUITION MEANS THEY MUST BORROW MORE MONEY. PA PROGRAMS ARE FINDING THAT THE DEGREE OF INDEBTEDNESS OF PA STUDENTS WHEN THEY GRADUATE HAS A STRONG BEARING ON THE TYPE OF PRACTICE THEY ENTER AND THE AREA OF THE COUNTRY IN WHICH THEY LOCATE.

AS YOU KNOW, PAs HAVE TRADITIONALLY GRAVITATED TO REGIONS OF THE COUNTRY THAT WERE DEEMED MEDICALLY UNDERSERVED. FOR THIS REASON, YOU FOUND A HIGH PERCENTAGE OF PAs WORKING IN VERY SMALL, VERY RURAL COMMUNITIES OR IN UNDERSERVED URBAN AREAS.

PROGRAMS ARE FINDING THAT PAs STUDENTS STILL WANT TO PRACTICE IN MEDICALLY UNDERSERVED AREAS BUT ARE FORCED, BECAUSE OF THEIR RELATIVELY HIGH LEVEL OF INDEBTEDNESS TO SEEK OTHER PRACTICE SETTINGS.

NOW THIS ISN'T TRUE FOR ALL PAs, MR. CHAIRMAN, AND I WOULD BE REMISS IF I LEFT YOU WITH THE IMPRESSION THAT PAs ARE LEAVING RURAL AREAS IN DROVES. THEY ARE NOT AND I FULLY

EXPECT THAT A SIGNIFICANT PORTION OF THE PA POPULATION WILL ALWAYS BE FOUND IN MEDICALLY UNDERSERVED AREAS. BUT WE DO SEE A CORRELATION AND IT IS ONE WE THINK CONGRESS SHOULD BE AWARE OF.

EDUCATIONAL OPPORTUNITIES

ANOTHER EXAMPLE OF HOW CUTBACKS IN FEDERAL FUNDING WILL AFFECT PAs IS IN THE AREA OF EDUCATIONAL EXPERIENCES. THE ON-SITE GERIATRIC LEARNING EXPERIENCES PROVIDED TO STUDENTS IS SIMILAR TO ROTATIONS OCCURRING IN MEDICALLY UNDERSERVED AREAS. ONE CAN ONLY EXPECT A REDUCTION ON FUNDS TO HAVE AN IMPACT ON THE FREQUENCY AND AVAILABILITY OF THESE ROTATIONS. FURTHERMORE THE LACK OF FEDERAL FUNDS WILL FORCE PROGRAMS TO RAISE TUITION AND FEES IN AN EFFORT TO PERPETUATE CONGRESSIONALLY MANDATED ROTATIONS IN HOME HEALTH CARE, GERIATRICS, HEALTH PROMOTION/DISEASE PREVENTION AND OTHER AREAS.

THE REDUCTION OF FUNDS AVAILABLE TO SUPPORT PA EDUCATION AND THUS STUDENT ROTATIONS IN UNDERSERVED AREAS COULD FURTHER AMPLIFY THE CORRELATION BETWEEN INDEBTEDNESS AND JOB SELECTION.

CONCLUSION

THE 4.8 MILLION DOLLARS AUTHORIZED FOR PHYSICIAN ASSISTANT EDUCATION IS NOT A GREAT DEAL OF MONEY IN THE TOTAL SCHEME OF THE FEDERAL BUDGET. BUT FOR PAs AND HEALTH CARE DELIVERY, IT MEANS A GREAT DEAL.

WE CONSIDER 4.8 MILLION A BARE BONES APPROPRIATION. IT WILL ALLOW PROGRAMS TO CONTINUE OFFERING QUALITY EDUCATION AT A RELATIVELY REASONABLE COST. ANY LESS, AND YOU WILL BEGIN TO SEE SERIOUS CONSEQUENCES FOR EDUCATIONAL OPPORTUNITIES FOR PAs AND THE FUTURE OF HEALTH CARE DELIVERY.

I WOULD ALSO LIKE TO NOTE, MR. CHAIRMAN, THAT AS PART OF THE REAUTHORIZATION SIGNED BY THE PRESIDENT, PA PROGRAMS ARE NOW REQUIRED TO OFFER COURSES IN GERIATRIC MEDICINE AS A CONDITION OF RECEIVING FEDERAL ASSISTANCE. THIS IS A REQUIREMENT THAT THE PROGRAMS WELCOME AND FEEL IS QUITE NECESSARY. INDEED, PROGRAMS ARE ALREADY INITIATING EDUCATIONAL EXPERIENCES IN THIS AREA.

WE STRONGLY URGE THE COMMITTEE TO APPROPRIATE THE FULL $4.8 MILLION AUTHORIZED AND WE LOOK FORWARD TO WORKING WITH YOU ON THIS GOAL.

THE ACADEMY APPRECIATES THIS OPPORTUNITY TO PRESENT ITS VIEWS AND I WOULD BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

STATEMENT OF DAVID BERGWALL, VICE PRESIDENT, ASSOCIATION OF UNIVERSITY PROGRAMS IN HEALTH ADMINISTRATION

Senator INOUYE. Our next witness is the vice president of the Association of University Programs in Health Administration, David Bergwall.

Welcome, sir.

Mr. BERGWALL. Mr. Chairman, my name is David Bergwall, and I am here on behalf of the Association of University Programs in Health Administration.

I would like to thank you for the opportunity to present testimony in support of two activities funded by this subcommittee, graduate programs in health administration and health administration traineeships.

By way of background, our association is a 38-year-old consortium consisting of 153 health administration programs in approximately 144 colleges and universities throughout the world. The primary objective of our programs is to strengthen and improve administrative and managerial leadership in the health care delivery system.

For the past several weeks, Mr. Chairman, this subcommittee has heard testimony from administration witnesses, like Secretary Bowen, who have emphasized the need to constrain rising health care costs, and, of course, we agree with the Secretary.

Over the past 15 years, national health expenditures has risen from $75 billion to more than $400 billion, with projections that in just 4 years health care cost will top $600 billion. It has got to the point, in fact, that the total cost of health care consumes 10.6 percent of our gross national product.

While these costs continue to spiral upward, we have seen dramatic changes in the patterns and organization of practice. In our view, Mr. Chairman, all this serves to underscore the importance of having well-trained administrators available to meet the demands of our health care system. For no matter how simple or how sophisticated we make it, whether practitioners are in oversupply or not, an efficient health care delivery system is dependent upon sound management. Health administrators, after all, have the ultimate responsibility for administering whatever cost containment measurements that you and your colleagues may devise. Responsibility also falls to the health administrator to grapple with the day-to-day problems associated with nursing shortages, physician availability, and technology assessment.

Unfortunately, management competence in health services is grossly uneven. The fact of the matter is that, first, two-thirds of the Nation's health administrators have not received adequate training and education in the field, and second, that the demand for professionally trained administrators in HMO's, PPO's, home health agencies, and rural hospitals far exceeds the supply.

What does it mean?

It means that the health professionals whose training you have helped support will not be fully productive. It also means that any cost containment system that is implemented will have limited effectiveness.

In short, Mr. Chairman, this country needs an effective health administration education system. Congress recognized this fact and last year adopted legislation reauthorizing these programs for 3 additional years. Unfortunately the President's budget seeks to terminate support, evidently without considering the consequences.

Mr. Chairman, health administration programs are the primary source for attracting young people to careers in health management, training them properly, and for upgrading present managers. Under the circumstances, the relatively small Federal investment in these programs—which, by the way, is matched by non-Federal funds—is well worth it.

While all the evidence points to the need for an expanded effort, we recognize that resources are limited. Our association, therefore, recommends that funding for health administration programs be continued at last year's appropriations level.

Thank you.

PREPARED STATEMENT

Senator INOUYE. Well, your presentation sounds logical and rational to me. I'll do my best to convince my colleagues.

Mr. BERGWALL. Thank you.

Senator INOUYE. Thank you very much, sir.

[The statement follows:]

STATEMENT OF DAVID BERGWALL

Mr. Chairman, my name is David Bergwall and I am here on behalf of the Association of University Programs in Health Administation. I would like to thank you for the opportunity to present testimony in support of two activities funded by this Subcommittee: Graduate programs in health administation and Health administration traineeships.

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Over the last 15 years, national health expenditures have risen from $75 billion to more than $400 billion, with projections that in just four years health care costs will top $600 billion. It is now to the point, in fact, that the total cost of health care consumes 10.6 percent of GNP.

And while costs continue to spiral upward, Mr. Chairman, we continue to see dramatic changes in the patterns of organization and practice.

In our view, Mr. Chairman, all of this serves to underscore the importance of having well-trained administrators available to meet the demands of our health care system. For no matter how simple or how sophisticated we make it, whether practitioners are in oversupply or not, an efficient health care delivery system is dependent upon sound management. Health administrators, after all, have the ultimate responsibility for administering whatever cost containment measures that you and your colleges may devise. Responsibility also falls to the health administrator to grapple with the day-to-day problems associated with nursing shortages, physician availability, and technology assessment.

Unfortunately, management competence in health services is grossly uneven, The fact of the matter is that, first, two-thirds of the Nation's health administrators have not received adequate training and education in this field, and second, that the demand for professionally trained administrators -- in HMO's, PPO's, home health agencies, and rural hospitals -- far exceeds the supply.

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While all the evidence points to the need for an expanded effort, we recognize that resources are limited. Our Association therefore recommends that funding for health administration programs be continued at last year's appropriations level.

Thank you, Mr. Chairman.

STATEMENT OF ROBERT V. CAPONE, EXECUTIVE DIRECTOR, AMERICAN ASSOCIATION OF COLLEGES OF PODIATRIC MEDICINE

Senator INOUYE. Our next witness is the executive director of the American Association of Colleges of Podiatric Medicine, Mr. Robert Capone.

Mr. CAPONE. Thank you, Mr. Chairman.

Senator INOUYE. Welcome, sir.

Mr. CAPONE. It's a pleasure to be here, and I appreciate the opportunity to present testimony before you and the subcommittee today.

My name is Robert Capone. I am the executive director of the American Association of Colleges of Podiatric Medicine.

In the way of background, I would like to begin by saying that ours is a nonprofit educational association representing the Nation's seven colleges of podiatric medicine and more than 2,700 students and residents.

As you know, Mr. Chairman, podiatric medicine is the medical specialty that focuses on the prevention, diagnosis, and treatment of diseases and disorders affecting the human foot. I suspect that most of us are also aware of just how important the human foot is to our daily lives. At one time or another, we have all heard those interesting facts like the feet have 52 bones, about one-fourth of the bones in the entire body, or that each day the feet absorb about half a ton of force.

What many people do not realize, however, is that foot problems may often be an early-warning sign of disorders elsewhere in the body, such as heart disease, diabetes, arthritis, and musculoskeletal disorders. From another perspective, when an individual experiences back pain, there is a good chance that the feet may be the source of the problem.

One last important fact, Mr. Chairman, as we all know, the elderly comprise the fastest growing segment of our population, and this group also happens to be the most vulnerable to foot problems. As a matter of fact, about 95 percent of the elderly suffer from painful, often debilitating foot ailments, and according to the National Center for Health Statistics, one-fourth of all nursing home residents cannot walk as a result of such ailments.

Given the demographic projections, society can expect a tremendous increase in the incidence of foot problems in our population. The question is, will we be able to meet the challenge?

For our part, the colleges of podiatric medicine are striving to prepare students for the profession. As a result of our efforts, the number of graduates has steadily increased over the past two decades. First-year enrollments, in fact, have risen by more than 80 percent in just the last 13 years, and over the same period minority enrollments have increased tenfold.

Despite this remarkable growth, the numbers indicate that we are barely keeping pace with the number of podiatrists who are retiring. Consequently, this country finds itself experiencing a severe shortage of podiatrists.

Today, for example, there are only 9,200 practicing podiatrists, 1 for every 27,000 Americans, as compared to 1 physician for approximately ever 600 persons. Furthermore, the U.S. Public Health Service predicts that the current shortage will extend at least into the 1990's when we will still be about 2,800 short of the minimum national need.

This shortage, of course, affects all of us, Mr. Chairman, but the hardest hit are the elderly and those who live in inner city and rural communities. For these individuals, the shortage means that they will have to postpone or perhaps forego treatment altogether, only to face more serious and often more expensive problems in the future. In many instances, that means society loses out—in lost wages, lower tax revenues, and in higher health care costs.

Mr. Chairman, last year we appeared before you and the subcommittee and asked that you continue to support health professions education and training programs, and you responded by doing just that, and we are very grateful for that.

Unfortunately, the President has once again proposed drastic reductions in this area. Once again, the administration has painted all disciplines with the same broad brush, claiming that there is an oversupply and implying that we would be foolish to continue support.

Mr. Chairman, apart from the very real and critical shortage I have already mentioned, I would only point out that by limiting the availability of student aid moneys, this budget proposal would undermine a basic tenet in our society—that of allowing every qualified person an opportunity to pursue a higher education. In practical terms, we would be turning back the clock to a time when only the wealthy could afford to practice medicine.

To conclude, we respectfully urge you to continue to support health professions loans, and we ask that you provide a minimum of $1 million to continue the remote site training program in podiatric medicine. The latter is proving to be an extremely effective program in attracting and retaining podiatric graduates in medically underserved areas.

PREPARED STATEMENT

Thank you very much, Mr. Chairman, for the opportunity to be here today.

[The statement follows:]

STATEMENT OF ROBERT V. CAPONE

My name is Robert Capone and I am Executive Director of AACPM, the American Association of Colleges of Podiatric Medicine.

In the way of background, let me begin by saying that ours is a nonprofit educational association, representing the Nation's seven colleges of podiatric medicine and more than 3,300 students and residents in 165 teaching hospitals.

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Given the demographic projections, Mr. Chairman, society can expect a tremendous increase in the incidence of foot problems in our population.

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Despite this remarkable growth, the numbers indicate that we are barely keeping pace with the number of podiatrists that are retiring.

Consequently, this country finds itself experiencing a severe shortage of podiatrists. Today, for example, there are only 9,200 practicing podiatrists--one for every 27,000 Americans--as compared to one physician for every 600 persons. Furthermore, the U.S. Public Health Service predicts that the current shortage will extend at least into the 1990's, when we will still be about 2,800 short of the minimum national need.

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Mr. Chairman, apart from the very real and critical shortage I have already mentioned, I would only point out that by limiting the availability of student aid monies, this budget proposal would undermine a basic tenet in our society--that of allowing every qualified person an opportunity to pursue a higher education. In practical terms, we would be turning back the clock to a time when only the wealthy could afford to practice medicine.

To conclude, we respectfully urge you to continue to support health professions loans and we ask that you provide a minimum of $1 million to continue the Remote site training program in podiatric medicine. The latter is proving to be an extremely effective program in attracting and retaining podiatric graduates in medically underserved areas.

Thank you, Mr. Chairman.

Senator INOUYE. Last year, the U.S. Army assigned one podiatrist to service all the men serving in the North Atlantic Treaty Organization. Last year, after nearly 50 years of suffering, I had the good sense to visit a podiatrist, so I have no in-grown toenails now, and you can be assured that you have someone who is very supportive here.

Mr. CAPONE. Thank you very much, sir.

Senator INOUYE. Thank you.

STATEMENT OF EDWARD R. JOHNSTON, FEDERATION OF ASSOCIATIONS OF SCHOOLS OF THE HEALTH PROFESSIONS AND DEAN, COLLEGE OF OPTOMETRY, STATE UNIVERSITY OF NEW YORK

Senator INOUYE. Our next witness is Edward R. Johnston, Federation of Associations of Schools of the Health Professions, dean, College of Optometry, State University of New York. Dr. Johnston.

Mr. JOHNSTON. Mr. Chairman, thank you. My name is Edward R. Johnston, I am the president and dean of the State College of Optometry, State University of New York. However, I am pleased to be here today to represent the views of the Federation of Associations of Schools of the Health Professions, FASHP, on appropriations for fiscal year 1987 and for Federal programs of support for health professions education. This includes student assistant programs and grants to institutions under title VIII and VII of the Public Health Service Act.

The federation represents over 300,000 students and 35,000 faculty members in some 1,600 schools located throughout the United States and Puerto Rico. These schools play a key role in assuring adequate health resources and research capabilities necessary to maintain the health of the people in this country; the young and the old of all income strata living in urban and rural settings. Members include colleges of nursing, osteopathic medicine, pharmacy, podiatric medicine, veterinary medicine, optometry, public health, and health administration.

Mr. Chairman, the President's budget for fiscal year 1987 proposes to eliminate funds for health professions training grants under titles VII and VIII of the Public Health Service Act. This action is premised on the belief that all health professions are in oversupply. While that may be true for some of the physician specialties, that is simply not the case for all health disciplines.

Our written statement cites available data which shows continuing shortages of many types of health professionals. The federation believes that these manpower shortages can best be addressed by the professions working with the Federal Government in a cooperative partnership. This has been the case in the past and we urge that it be continued.

Not only is there a need to increase the number of many of the health professionals, but particular attention needs to be paid to what types are needed and how they are trained. This is essential if we are to respond to the changing modes of health care delivery and evolving medical needs.

The grant programs under title VII and VII of the Public Health Service Act enable our educational institutions to work with the Government in order to respond to the rapid changes now occurring in the health delivery system. These problems are national in scope and should be addressed at the Federal level.

Continued funding for these grant programs helps solve only part of the problem. Applicant pool and enrollment in the health professions continues to decline as a result of increasing costs for the education and student indebtedness. Minority and disadvantaged populations are underserved, severely underserved, and severely underrepresented. If students are to continue to have an opportunity to study in the health field, various forms of Federal financial assistance must be continued. Of particular concern are the proposed reductions in the HEAL guarantees proposed in the President's budget.

In conclusion, Mr. Chairman, let me note that the future manpower needs will be influenced by the changing health care needs. Policymakers must consider the necessary supply of all health professionals and their interaction, their interdependence and, in some cases, their interchangeability. The health care professions and Government share a responsibility to strive for the best health care system possible. To deny resources to one portion of the partnership is to risk the loss of opportunity in prevention and cost containment, and under service to groups with special needs such as the elderly and the economically disadvantaged and rural Americans.

For these reasons, Mr. Chairman, the federation recommends that fiscal year 1987 funding levels for health professions educational assistance programs be maintained at the 1986 appropriation levels. Thank you very much.

Senator INOUYE. Doctor, we will do our utmost to make certain that the appropriate amounts are appropriated.

Mr. JOHNSTON. Thank you.

STATEMENT OF CLYDE B. JENSEN, PH.D., SECRETARY/TREASURER, AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE

Senator INOUYE. Our next witness is Dr. Clyde Jensen, the secretary/treasurer, American Association of Colleges of Osteopathic Medicine. Dr. Jensen, welcome, sir.

Mr. JENSEN. Thank you. Mr. Chairman, my name is Clyde Jensen, I am the president of the West Virginia School of Osteopathic Medicine and a member of the board of governors of the American Association for Colleges of Osteopathic Medicine. Like those who have preceded me, I am here today to speak on behalf of the Nation's health care programs and continued Federal funding for those programs.

I am aware of the efforts of this committee to restore funding to our health care programs, our health professions programs, through function 550, and we are especially grateful for the efforts of members of this committee in restoring approximately $600 million to those programs.

I wish to convey to you on behalf of America's 15 osteopathic medical schools the urgent need in osteopathic medical education circles to continue funding for student financial aid, and for some of the educational programs that take place in our rural communities.

The osteopathic medical profession is perhaps one of the most comprehensive health care professions in the United States. Our physicians are trained and licensed to prescribe drugs, perform surgery, engage in psychotherapeutic means. Additionally, they have specialized training in the use of the musculoskeletal system in diagnosing and treating various types of diseases.

Because of the comprehensive nature of the osteopathic physician, he tends to perform very well in rural settings in small communities where perhaps only one physician can be sustained. For that reason, the vast majority of our osteopathic physicians practice in some of the primary care fields such as family medicine, and most of those practice in small towns and rural areas that might otherwise be medically underserved.

We know that there are about 25,000 osteopathic physicians practicing in the United States today; that's approximately 5 percent of America's health care force, but we estimate that they deliver health care services to approximately 30 million Americans, or well over 10 percent of America's population. The reason for this disparity is the nature of the practice in which they engage. I simply wish to point out to you that the role of America's osteopathic physicians is very important, particularly in our rural areas and small towns.

We're successful in training young people to go into those areas to practice because we strategically select them from those rural and small town areas, and we train them to the extent possible in those areas. Because they come from small towns, our students oftentimes come from financially disadvantaged backgrounds. Our statistics show that the average indebtedness of an osteopathic medical student today is in excess of $40,000 and we project that the average indebtedness will exceed $58,000 by 1987.

We also know that about 17 percent of the families from which our osteopathic students come have incomes of less than $10,000, and over one-half of them come from families with incomes of less than $30,000. They would be unable to afford a medical education if it were not the assistance that the Federal Government provides to student financial aid.

We train our students to the extent possible in rural areas, and if our health professions programs were eliminated or drastically curtailed, we would no longer be able to provide such services as free clinics for the poor and unemployed in Iowa and Illinois, and for medical services to native Americans in Oklahoma, where we have an osteopathic medical school, or to migrant farm workers in Florida or to foreign families in Missouri. We train our students in those rural communities with the expectation that they will return one day to practice in those communities.

So we simply urge you to continue the support that you have rendered in the past on behalf of our health professions programs, and particularly funding for title VII programs and student financial aid.

Senator INOUYE. What is the income level of osteopathic physicians?

Mr. JENSEN. I can tell you that in our school, our graduates will probably have an average income the first year after completing their postdoctoral training in the neighborhood of $40,000 per year. Now that probably would range from a low of about $25,000 per year for those who are starting their practices in rural areas, to a high of about $85,000 per year for those who have gone into larger communities to practice with established practitioners.

It's interesting to note that the deciding factor as to which of those two choices they will finally accept depends to a large extent upon their debt load. Those who have large indebtedness can be more easily attracted to the urban areas to practice where the practice is more lucrative, but also where their services are less desperately needed.

PREPARED STATEMENT

Senator INOUYE. Thank you very much, sir. We will place your statement in the record at this point.

[The statement follows:]

STATEMENT OF CLYDE B. JENSEN

My name is Clyde B. Jensen. I have an earned Ph.D. and am President of the West Virginia School of Osteopathic Medicine. I'm also Secretary/Treasurer of the American Association of Colleges of Osteopathic Medicine (AACOM). I am pleased to be here today to present the views of AACOM on fiscal year 1987 funding for programs of health professions education support, including student assistance and grants to schools under Title VII of the Public Health Service Act.

Mr. Chairman, over the years osteopathic medicine has pursued a commitment to provide family and primary medical care to smaller communities throughout the country. Approximately half of the osteopathic physicians in practice today are in communities of under 50,000. About 80 percent of America's osteopathic physicians practice in one of the primary care disciplines.

My own school in West Virginia is dedicated to providing the finest family physicians for West Virginia and its Appalachian neighbors. In fact, it was created for that very purpose in 1972. The founding college in Kirksville, Missouri, has been working to meet rural health needs for more than 94 years. While each of the 15 osteopathic medical colleges is unique, they are united in their desire to produce physicians who have this orientation to family medical care. We realize that the need for primary care physicians is a national one and we are putting forth our best efforts to help meet that need.

Over the years, our colleges have been fortunate to forge partnerships with the federal and state governments, as well as with private sources, to develop programs to further our colleges' public interest missions. To date, I believe these programs have been successful in building stronger institutions, capable of training high caliber osteopathic physicians. These programs also help our colleges provide medical services to those in need in their communities.

For example, the University of Osteopathic Medicine and Health Sciences in Des Moines, Iowa, offers free medical care to unemployed people in the area. A federal family practice grant under Title VII helps support staffing in the clinics where these services are provided. Similar grants at the Chicago College of Osteopathic Medicine also help support faculty and staff to work with students and patients in their ambulatory clinics.

An Area Health Education Center grant helps the Ohio University College of

Osteopathic Medicine provide medical care to rural underserved areas of southeastern Ohio. The Oklahoma College of Osteopathic Medicine and Surgery, under an AHEC grant, provides medical services to Native Americans and other minority groups in need. The Southeastern College of Osteopathic Medicine in Florida serves migrant families in that state under another AHEC grant. The Kirksville College of Osteopathic Medicine in Missouri has applied for an AHEC grant which, if approved and funded, will be used to provide medical care, stress clinics and emotional support to farm families facing economic crisis.

In each of these examples, and in others too numerous to mention, osteopathic medical students work in these settings as part of their clinical experience. Thus, they are exposed to the physician role models who encourage them to seek to practice primary care. At the same time, they are learning medicine and providing services to patients. These federal funds not only expand our ability to provide care to those who need it now, they also help us train new generations of primary care physicians to make sure we can meet medical needs in the future.

Unfortunately, the partnership our colleges have formed with the federal government is now in jeopardy. The President's fiscal year 1987 budget proposes to eliminate all funding for health professions grants and to rescind funds already appropriated by Congress in 1986. The Senate Budget Committee proposal assumes a 50 percent reduction in these funds. Were this to happen, our colleges would be hard pressed to maintain these rural medical care programs. Moreover, AACOM itself might no longer be able to operate its Health Careers Opportunity Program (HCOP) which seeks to identify students from minority and disadvantaged groups who are interested in health professions careers. This program has been in operation since 1978 and was expanded in 1982 to include a summer-study program.

Students who might not have entered a health professions career have been encouraged to do so. Since 1982, 67 percent of students in HCOP have applied to enter a health professions school.

If these funds are lost, or substantially reduced, our colleges would not have access to monies to improve their family medicine programs. Federal health professions grants have been an important source of assistance to our colleges seeking to further strengthen their primary care training. As an example, the

Chicago College of Osteopathic Medicine has grants under Title VII to help strengthen predoctoral and post-doctoral programs in family medicine, thus reinforcing the College's mission to train primary care physicians. Kirksville College has just been awarded funding for family medicine programs. At Michigan State University College of Osteopathic Medicine, these federal funds have been used to strengthen adjunct faculty involved in clinical training.

Ohio University College of Osteopathic Medicine also participates in these grants and they have produced results. Seventy four percent of their graduates in practice are practicing primary care. Sixty two percent of their graduates are providing care in Ohio, many of them in towns under 50,000 population.

I know the Administration, and some others, argue that federal support for health professionals, especially physicians, is no longer needed in light of expected surpluses. However, if that is so, why does Congress continue to express concern about shortages of primary care physicians? Why were these grant programs reauthorized last year? Why does this Subcommittee continue to recommend appropriations for these programs?

I believe the answer is clear. You and other Members of Congress recognize that needs still exist for primary care; for service to medically underserved areas; and for people in trouble. You see that these programs contribute to meeting those needs and that they should be continued.

Mr. Chairman, I am proud of the work our colleges do and I believe they have made good use of these grants in pursuit of important national health goals. But, I am also mindful of the financial constraints you here in Congress must face as you try to balance many competing demands. In view of the current budget situation, we would seek only a continuation of current funding levels, with restoration of the 4.3 percent Gramm-Rudman-Hollings cuts. Current funding is modest, but extremely helpful. It often makes the difference between beginning a new project, completing an old one or abandoning the idea.

The raw material for an educational institution is its faculty and students. The grant programs I have just discussed are used to strengthen faculty and curriculum in order for our colleges to perform their tasks of teaching and providing services more effectively. However, without the right mix of students, we would not succeed in our educational mission.

As I mentioned earlier, our West Virginia college has a special dedication to providing family physicians to our region. Accordingly, we seek students with a special interest in providing that care in rural communities. Many of these students are from these areas themselves and mant do not have the personal or family resources to pay the costs of an osteopathic medical education. They must rely on financial assistance, much of it federal. The availability of various student assistance programs at the federal level has made it possible for our college, and other osteopathic medical colleges, to offer an education to a broad spectrum of students. Those opportunities will evaporate without a continued Federal commitment.

Let me provide you with some statistics that dramatize the dependence of our students on federal education assistance. Tuition and living expenses at a private osteopathic medical college can exceed $19,000 a year. At state schools, the average costs are just over $10,000 for residents and over $12,000 for non-residents. By the fourth year, the average costs have risen to $13,500 for residents and $15,000 for non-residents. Faced with these costs, ninety three percent of seniors in all osteopathic medical colleges expect to graduate with sizeable debts from financing their education. In 1984, that debt averaged $40,000. For students graduating in 1987, we anticipate an average indebtedness of $58,000.

This increase in debt results from two factors. First, the cost of an education continues to rise, despite efforts by our schools to hold tuition costs down. Kirksville, for example, has not significantly increased its tuition for four years and in the next academic year will reduce its tuition. The second reason for increased indebtedness results from the loss of scholarship funds, such as the National Health Service Corps Scholarships. As scholarships disappear, students shift to loan programs to finance their education. We noted a 16 percent increase in the total number of loans from 1983 to 1984.

There are a number of federal loan programs, but for our students, the most important ones have been the Guaranteed Student Loan (GSL) program, National Direct Student Loans (NDSL), the Health Education Assistance Loans (HEAL) and the Health Professions Student Loans (HPSL). I suspect that other health professions students are similarly situated. Over 86 percent of federal loans used by our students come from these sources. Both NDSL and HPSL have been reduced substantially in availability.

We are particularly concerned by the President's recommendation to reduce HEAL support to $100 million in fiscal year 1987. Fiscal year 1986 guarantees were in the range of $275 million, which is a strong indication of the need for assistance that exists. To slash those guarantees by nearly two-thirds would be devastating to our students. Approximately 50 percent of our students' loan funds come from the HEAL program. Approximately 38 percent comes from GSL. However, as we see more restrictions being placed on GSL, we see a shift to the HEAL funds. For example, in the Ohio College, the use of HEAL quadrupled from 1983 to 1985. This is occuring despite the fact that HEAL repayment can be quite a burden because of high interest rates. We are concerned over the impact that this may have on career choices our students will make. In the 1984-1985 academic year, our students borrowed over $30 million under this program. I would note here proudly that the HEAL default rate among osteopathic medical students is quite low. In fact, it is the lowest among all health professions, namely 3.61 percent.

Mr. Chairman, our colleges want to make sure that they are open to all students. To a great degree we have succeeded. Minority applications and admissions continue to rise, with enrollment increasing in 1983-1984 by 20 percent among freshmen. Women now exceed 25 percent of total enrollment. This is progress we want to continue. Over 17 percent of senior students in 1984 reported parents' incomes of less than $10,000. Fifty percent came from families with incomes below $30,000. Certainly these students could not have turned to their families for more support.

We think that part of our mission is to provide educational opportunities to students who will make good osteopathic physicians, regardless of economic or ethnic background. Those opportunities become reality only because of federal assistance to students. Frankly, there is no good substitute source of money. Our colleges are working vigorously with the states and with private sources to generate additional sources of student support, but it is still not enough to supplant a sharp reduction in federal assistance. The endowments of many of our schools are not large enough to generate adequate scholarship funds. We strongly urge that student assistance programs be maintained at current levels.

In conclusion, let me reiterate the main goal of the colleges of osteopathic medicine -- to train physicians to provide comprehensive family health services to those in need and in geographic areas of the country where the need is great. The federal government has been an important partner in that effort. We believe that the federal programs I have discussed have contributed importantly to our success thus far. However, more work remains. There is still a need for primary care physicians. There are still parts of the country with acute medical service needs. There are still students who aspire to meet these needs, but require financial help to pursue those aspirations.

We ask this Subcommittee to help us continue our work by ensuring adequate funds for programs under Title VII of the Public Health Service Act and for federal assistance programs to students.

STATEMENT OF JERROLD M. MICHAEL, PH.D., U.S. ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH, PRESENTED BY DR. MICHAEL GIMMEL

Senator INOUYE. Our final witness was Dr. Jerry Michael representing the U.S. Association of Schools of Public Health, but Dr. Michael cannot be here. He is presently working with members of the world health organizations. So in his stead we have Dr. Michael Gimmel, executive director of the Association of Schools of Public Health.

Welcome, sir.

Dr. GIMMEL. Thank you, Mr. Chairman. I shall be very brief. As you know, Dean Michael asked me to extend his apologies for not being here today. With your permission, I will read his testimony.

The presentation by Dr. Edyth Schoenrich in favor of all of the schools of public health is, of course, strongly endorsed by the University of Hawaii, and I am pleased to have such a good friend and valued colleague as Edyth Schoenrich representing our interests.

I would like to supplement her comments by special testimony in three areas: one, supplemental appropriations for emergency medical services as they relate to children's health; two, support for programs that are of assistance to minority and underrepresented individuals; and three, the appropriations to the Centers for Disease Control regarding creation of several centers for health promotion and disease prevention.

Emergency medical services activities provide an important life line for the advanced medical services delivered through our hospitals in Hawaii. As chairman of the Board of Kuakini Health Systems—I hope I pronounced that correctly, Senator.

Senator INOUYE. Beautiful.

Dr. GIMMEL. I have personal knowledge of the beneficial effects of these services, particularly as they relate to children of Hawaii.

Of the 29 proposals submitted, there was only enough money in fiscal year 1986 to fund support for four projects. I urge that fiscal year 1986 supplemental funds be appropriated for this important program.

The Health Careers Opportunity Program [HCOP] under the Bureau of Health Professions of the Public Health Service provides for the training of disadvantaged and potentially underutilized minority individuals. This support program, which we are proud to have at the University of Hawaii, enables us to conduct a special training program to address the deficiencies in these individuals' academic backgrounds. This preparation assists them in becoming competitive for admission to our regular academic degree program, and subsequently, competent to productively serve their own people in the health field.

It has been my pleasure to be present at the graduation of significant numbers of Hawaiian, Filipinos, Samoans, Micronesians, and a host of recent immigrants to Hawaii from Southeast Asia who, without this kind of special support, still would be relegated to minor jobs. I urge you to consider support for the HCOP, as they call it, program.

Finally, Senator Inouye, Dean Michael wishes me to remind the committee of the intent of Congress' language that has been introduced by you into all the deliberations surrounding the passage of the legislation which provides the Centers for Disease Control the opportunity to fund several health promotion and disease prevention centers in the United States. I quote, "That intent of Congress language includes specific wording calling for one of these centers to be an international center serving the Pacific Basin and Southeast Asia." The intent of that congressional direction is to permit one of these centers to be established at the University of Hawaii School of Public Health.

For the past several years, we have established a receptive framework for that center and have in place an ongoing relationship with all of the schools of public health in Asia and the Pacific, covering an area that includes one-half the population of the globe. This includes the Philippines, Indonesia, Thailand, Nepal, Sri Lanka, Malaysia, Korea, Singapore, the People's Republic of China, and Hawaii as the United States representative.

We stand ready to serve all the States of the United States in cross-cultural health promotion and in its international health outreach through the identification of an international center at the University of Hawaii.

Thank you, Senator Inouye, for the opportunity to present this special testimony by Dean Michael.

PREPARED STATEMENTS

Senator INOUYE. Dean Michael should be pleased with your presentation, sir. Thank you very much. Your statement will be included in the record at this point along with other statements for the record on appropriations for the Health Resources and Services Administration.

[The statements follow:]

STATEMENT OF JERROLD M. MICHAEL

Senator Inouye, I am pleased to be able to present this testimony to you in your post as Acting Chair because much of what I will say that is related to the State of Hawaii and the School of Public Health at the University of Hawaii is not only well known to you but covers programs for which you have provided policy leadership.

The presentation made on this day by Dr. Edyth Schoenrich in favor of the Association of Schools of Public Health sets out our interests and concerns regarding Institutional Support, Student Traineeships, Preventive Medicine Residencies, the Older Americans Health Promotion and Disease Prevention Projects, NIOSH Educational Resource Centers, and the Centers for Health Promotion and Disease Prevention. That presentation, made in favor of all the schools of public health, is of course strongly endorsed by the University of Hawaii and I am pleased to have had such a good friend and valued colleague as Edyth Schoenrich representing our interests.

I would like to supplement her comments by special testimony in three areas: Appropriation for emergency medical services as they relate to children's health, support for programs that are of assistance to minority and underrepresented individuals, and the appropriation to the Centers for Disease Control regarding creation of several Centers for Health Promotion and Disease Prevention.

Emergency medical services activities provide an important lifeline for advanced medical services delivered through our hospitals in Hawaii. As Chairman of the Board of the Kuakini Health System, I have personal knowledge of the beneficial effects of these services, particularly as they relate to the children of Hawaii. I urge that these appropriations be supported in order to glean the major benefits that are so important to our state and our society in general.

The Health Careers Opportunity Program, under the Bureau of

Health Professions of the Public Health Service, provides for the training of disadvantaged and potentially underutilized minority individuals. This support program, which we are proud to have at the University of Hawaii, enables us to conduct a special training program to address deficiencies in these individuals' academic backgrounds. This preparation assists them in becoming competitive for admission to our regular academic degree programs and, subsequently, competent to productively serve their own people in the health field. It has been my pleasure to be present at the graduation of significant numbers of Hawaiians, Filipinos, Samoans, Micronesians, and a host of recent immigrants to Hawaii from Southeast Asia who, without this kind of special support, will be relegated to minor jobs in the tourist industry. Dr. Clay Simpson and his colleagues should be commended for the work they are doing in the Public Health Service and I urge you to continue the support of those programs.

Finally, Senator Inouye, I need not instruct you but this becomes an opportune moment to remind the committee of the intent of Congress language that has been introduced by you into all the deliberations surrounding the passage of the legislation which provides the Centers for Disease Control the opportunity to fund several health promotion and disease prevention centers in the United States. That intent of Congress language includes specific wording calling for one of these centers to be an international center serving the Pacific Basin and Southeast Asia. The intent of that congressional direction is to permit one of these centers to be established at the University of Hawaii School of Public Health. For the past several years we have established a receptive framework for that center and have in place an ongoing relationship with all of the schools of public health in Asia and the Pacific covering an area that includes half the population of the globe. This includes the Philippines, Indonesia, Thailand, Nepal, Sri Lanka, Malaysia, Korea, Singapore, the People's Republic of China, and Hawaii as the U.S. representative. We stand ready to serve the states of the United States in cross-cultural health promotion and in its international health outreach through the identification of an international center at the University of Hawaii.

Thank you, Senator Inouye, for this opportunity to present this special testimony.

LETTER FROM WILLIAM W. HAMILTON, JR., DIRECTOR, WASHINGTON OFFICE, PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.

May 22, 1986

Senator Lowell Weicker
Chairman
Subcommittee on Labor - HHS - Education Appropriations
131 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Weicker:

We appreciated the opportunity to testify before the Appropriations Subcommittee on Labor-HHS on May 6. Under your leadership, the subcommittee has been unwaivering in its support of the Title X family planning program, and as always, we are pleased to provide the subcommittee with any information which may be useful to this effort.

During the May 6 hearing, Senator Inouye invited Planned Parenthood to submit additional information for the record in response to the testimony of James Deger from the American Life League (A.L.L.). We ask that this letter be included in the record.

It is interesting to us that the A.L.L. used the bulk of their time before the subcommittee to attack Planned Parenthood Federation of America (PPFA) and then asked permission to submit at some later date specific recommendations for improving the Title X program. Although the specific claims about Planned Parenthood are not new—some of Mr. Deger's citations date back to 1971—the quotes are out of context, and bear no relevance to the issue before the subcommittee, namely FY87 funding for Title X. We would be happy to provide the subcommittee, upon request, with the complete text of the documents cited by Mr. Deger in his irresponsible attack against Planned Parenthood.

The purpose of this letter, however, is to correct several important errors of fact about the Title X program contained in Mr. Deger's testimony. First, the A.L.L. states that Planned Parenthood Federation of America is the largest recipient of Title X funds. In fact, PPFA receives no Title X funds. Of the 86 Title X direct grantees, only six are Planned Parenthood organizations. Local Planned Parenthood organizations together receive about $30 million of the total $142.5 million appropriation, or roughly 21% of the funds. Nationally, state and local health departments serve 40% of the Title X clients; local Planned Parenthoods serve 27%; hospitals, 13%, and a variety of other agencies such as HMO's, neighborhood health centers and free clinics, 20%.

Second, the A.L.L. cites a 1983 Government Accounting Office report as "proving" that through accounting and other technical procedures a number of Title X clinics receive funds and still perform abortions, counsel women for abortions, or refer for abortion services. Since its enactment in 1970, Title X has prohibited the use of federal funds to perform abortions. The GAO reported in September 1983 that all Title X clinics studied were operating in full compliance with the law. In testimony before the House Subcommittee on Health and the Environment in both 1984 and 1985, DHHS officials specifically reaffirmed that clinics were in full compliance with the prohibition.

Title X clinics do, however, provide counseling and referral for abortion as required by the program guidelines. Women specifically seeking information about the management of an unintended pregnancy must be told about all of their options -- in accordance not only with federal regulations but also with medical standards promulgated by the American Medical Association and the American College of Obstetricians and Gynecologists. Clinics affiliated with Planned Parenthood do not operate differently in this regard than do other clinics run by state and local health departments, hospitals, or other agencies.

Third, the A.L.L. claims that Catholic-affiliated organizations cannot receive Title X funds because of their moral objections to artificial birth control. As you know, any public or private non-profit organization can participate in the Title X program if it is willing to comply with the program regulations and guidelines. Specifically, organizations which participate in the Title X program must provide, either directly or through referral, the broad range of contraceptive services, including natural family planning. A number of Catholic affiliated organizations, including Providence Hospital Center for Life in Washington, D.C., the Pittsburgh Catholic Diocese, and St. Joseph's Hospital in Albuquerque, to name just a few, currently receive Title X funds.

Fourth, Mr. Deger claims that Planned Parenthood clinics maintain a "sneak policy" of letting minors receive services without parental consent. In fact, Planned Parenthood does support the principal of confidential services to all patients, including minors. All Title X clinics are required by law to provide confidential services to teens. Various court decisions have struck down state and local government mandatory parental notification and consent requirements for minors. In 1981, DHHS mandated that Title X projects require notification of parents within ten days following the provision of Title X services to minors. The U.S. District Court for the District of Columbia ruled in March 1983 that such a requirement was illegal and violated the Title X statutory requirement of confidentiality of services to minors.

Finally, the A.L.L. testimony cites a poll conducted for Planned Parenthood by Lou Harris. As noted in our testimony, based on this poll, 84% of Americans consider teen pregnancy to be a serious problem. The majority of Americans cite open communication about sex education and birth control as two key things parents should do to alleviate the problem of teenage pregnancy. While it is true (and not surprising) that many parents expressed ambivalence about their children receiving birth control without their knowledge, at the same time, parents expressed the need for outside help when it came to informing their children about birth control and a majority agree that making contraceptives more difficult for teens to obtain would cause more teen pregnancies. Clearly, the American public is crying out for a solution to this problem, and the Harris poll provided an important insight into what the public believes will be necessary. We submitted the complete poll with our testimony.

Again, Mr. Chairman, we appreciate the opportunity to correct the inaccuracies in the A.L.L. testimony with respect to the Title X program and we would be happy to provide the committee with any additional information that may be useful.

Sincerely,

Bill Hamilton

William W. Hamilton, Jr.
Director, Washington Office

STATEMENT OF MARY MURPHY, REGISTERED NURSE, PEDIATRICT NURSE PRACTITIONER, NATIONAL ASSOCIATION OF PEDIATRIC NURSE ASSOCIATES AND PRACTITIONERS

Mr. Chairman, members of the committee, I am happy to be here today to present testimony. I am Mary Murphy, a registered nurse and a pediatric nurse practitioner speaking on behalf of the National Association of Pediatric Nurse Associates and Practitioners (NAPNAP) and the Nurses' Coalition for Legislative

Action (NCLA). Attached for the record is information about NAPNAP and the Coalition. Together, with many other nursing organizations and associations, we are working to obtain full funding or $55.350 million in fiscal year 1987 for the nursing education programs and $18.5 million for the National Center for Nursing Research. My testimony will address the nursing education programs. Peggy McFadden's testimony will address the nursing research programs.

Funding support for the nursing education programs and the center is essential. The Nurse Education Amendments of 1985 authorized funds for advanced nursing education. These education programs produce the nurses that practice as patient care specialists, health care administrators nursing faculty and nurse researchers. Only 5.6 percent of nurses meet the Institute of Medicine's recommendations for the number of specialty nurses needed to meet the health care needs of our country. By 1990, the country will need 358,300 nurses with graduate education. If the current trend continues there will only be 118,900 qualified nurses--less than half the demand.

The health care system has dramatically changed over the past 20 years. In the past, it was viewed primarily as the diagnosis and cure of illness. Hospitals were the major site of health care delivery and most ambulatory care was given in physician offices and/or hosptial out-patient clinics. Nursing practice was largely illness oriented. Their primary work place was in hospitals--except for the public health nurses. Forty seven percent of all health care expenditures were financed by the patient and his or her family.

Today's health care focus is more preventive than in the past and includes promotion, prevention and maintenance of health as well as diagnosis and treatment of illness. Health care is increasingly delivered in the community rather than hospital settings. Ambulatory care is increasingly offered in neighborhood health centers, free standing clinics and in specialty and multispecialty practice settings. The lengths of stay in hospitals has decreased due to economic incentives from third party payors. The result is a higher percentage of sick patients in our community--higher than ever recorded in our past. Physicians comprise one of several provider groups involved in primary health care delivery. They continue as primary providers in the diagnosis and treatment of major illnessess. But, nursing practice encompasses promotion, treatment and rehabilitative services across the health illness and wellness spectrum including direct personal care, health education, counseling and therapy. Nursing services provided in the community have expanded to meet the complex and diversified health and illness needs of the people.

The point is that the "advanced and specialty " nurses have been, and have a continuous need to be, educated to meet the demands of our current health system. Nurses, when properly educated and licensed can, and do, the following:

- deliver anesthesia
- provide pre-natal care and deliver babies
- perform physical exams, developmental assessments, order laboratory tests and health screening measures--like vison and hearing screenings
- teach families about normal childhood growth and development, safety and nutrition
- counsel families
- assess, manage and treat acute and minor childhood and adult illnesses
- manage chronic illness

- and refer to other health professionals when appropriate like physicians, and other community agencies.

The professional nurse is a recognized, essential practitioner in providing health care to our people. In the struggle to provide high quality, financially feasible, accessible health care to the young and old, sick and well, the nurse stands out as the professional, who practices effectively in every health care field.

In order to continue to provide and improve quality nursing care, combining high technology and human touch, nurses need to be educated beyond their current education. Currently only 5.4 percent of nurses have advanced preparation to provide direct care as clinical nurse specialists/ nurse practitioners, nurse therapists, nurse midwives, nurse anesthetists or as teachers, consultants, administrators, and researchers. The nurse education programs and the nursing research center provides funds for programs to further educate nurses in these essential areas.

Federal support for nursing education and research programs has provided the nation's citizens with advanced nursing care brought about through advanced education. It must continue! Nurses average compensation is not high, and universities are in a funding crisis, therefore funding for advanced educational programs is crucial. At a relatively low cost, nurses can be prepared in these areas to meet the needs of patients in the 21st century. The patient, the country, and the national budget will benefit by providing nurses, who help individuals, who promote health, who prevent illness, care for the elderly, for the sick and for the young.

We are appreciative of your support in the past, and respectfully urge that this committee recommend funding at the full authorization levels for the nursing education programs in the following amounts:

Advanced nurse Training	$17 million
Nurse practitioner & Midwifery	$12 million
Nurse Anesthesia	$ .800 million
Traineeships	$12.25 million
Special Projects	$9.5 million
Demonstration Projects	$2.7 million
Faculty Fellowships	$1.1 million
TOTAL	$55.350 million

For the National Center for Nursing Research at the National Institutes of Health we are requesting a total of $18.5 million be appropriated and allocated for:

Administration	$5.5 million
Nursing Research Grants	$10 million
Training	$3 million
TOTAL	$18.5 million

As the largest group of health care professionals in the United States, nurses are and will continue to be at the forefront of our health care system. An investment now in nursing graduate education will help to ensure that nurses receive the advanced education needed to meet the needs of the ever changing health care system.

Your favorable consideration of fully funding these programs would be appreciated. Thank you for the opportunity to appear before you . I would be pleased to answer any questions you might have.

STATEMENT OF J. JOSEPH SPEIDEL, M.D., M.P.H., VICE PRESIDENT, POPULATION CRISIS COMMITTEE

The Population Crisis Committee (PCC) greatly appreciates the opportunity to present our views to the subcommittee on the issue of contraceptive research and development. PCC is a private non-profit organization which has sought for 20 years to strengthen political and financial support for international family planning. We strongly support efforts to develop new and improved methods to regulate fertility and advocate a greater commitment of funds and manpower to this critical task.

This presentation will explore: 1) why better contraceptive technology is important; 2) what is blocking the use of current methods; and 3) what is needed to advance development of new and improved means of fertility control.

Fertility Regulation Technology plays a Critical Role in International Family Planning Success

Both nations and individuals around the world want family planning. Increasingly, they recognize that properly spaced childbearing, limited to desired numbers, offers important benefits to maternal and child health and contributes to the social and economic advancement of both families and nations.

A substantial body of evidence indicates that the nature of the available fertility control technology has a highly important impact on the cost, speed and effectivness with which family planning programs can successfully be provided and used by couples who wish to control their fertility. Evidence supporting this assertion comes from an examination of the progress of national family planning efforts and from careful in-depth research on smaller scale family planning projects.

In the early 1960's, introduction of the pill and the IUD, which allowed a separation of contraception from sexual activity, had a profound impact on the ability of many couples to control their fertility effectively. This improvment in fertility control efficiency was most pronounced among the poor, both in developed countries and among Third World peoples living in the "culture of poverty."

More recent advances have had a similiar beneficial impact. For example, new methods of female sterilization were developed in the early 1970's using laparoscopy and mini-laparotomy. For the first time, female sterilization was possible as a simple out-patient procedure carried out under local anesthesia, thereby becoming practical in the Third World. Since 1970, the number of women protected by sterilization has increased dramatically, from about 10 million to 96 million.

Intensive studies of discrete family planning projects also reveal the profound impact of contraceptive technology on family planning success. Introduction of each new fertility control method results an incremental increase in total use. New methods may cause a small proportion of users to abandon a method previously adopted, but the net result is a substantial increase in the total prevalence of use of family planning.

Today's methods, although generally safe, still cause too many unpleasant side effects - the principle cause for method switching and discontinuation. The record of organized family planning efforts in many countries demonstrates that sustained, high levels of contraceptive prevalence are more easily achieved if a wide range of birth control choices are offered. The variety increases the odds that at least one method will be attractive to a potential user. An expanded array of new and improved contraceptive methods would make the job of reaching the millions who do not use contraception significantly easier, both in the developed and in developing countries.

Barriers To Use of Current Methods

Couples in many countries must wage the battle against unwanted fertility with unnecessary legal and economic limitations on their contraceptive armamentarium. These limitations also have a damaging impact on contraceptive development efforts. Profit-making drug companies are increasingly reluctant to invest in contraceptive research when it is likely that unnecessary roadblocks will keep the products they develop from widespread use.

In the United States we are falling behind in the race between the loss of proven contraceptives and the introduction of new ones. The array of forces holding back contraceptive availability and research includes problems with product liability, agitation by anti-family planning activists, pressures brought by radical feminists and consumer groups, and the cautious and lengthy procedures required by the U.S. Food and Drug Administration (FDA).

All of these factors have some impact overseas as well. A drug or device kept off the U.S. market, e.g., Depo-Provera, or taken off the U.S. market, e.g., the Copper-T IUD, reduces the willingness of program directors and potential users to accept the method overseas. Ongoing controversy about contraceptives in the U.S. has given Third World countries the false impression that current contraceptives are unsafe.

Product Liability Litigation: An avalanche of law suits against the Ortho and the G.D. Searle pharmaceutical firms led them to stop selling their widely used IUDs in the United States. The cost of litigation, not problems of product safety, prompted their decision. The results are 1.4 million American women now without replacements for their IUDs and the contraceptive choices for all U.S. women have become severely limited. In the meantime, Europeans, Canadians and citizens of many developing countries have IUD options not available in the United States, including The Multiload and the FDA approved Copper-T 380A.

So far the pill remains available despite numerous lawsuits. A principle reason is that repeated sales of high priced monthly cycles of pills generate the sizable profits the drug companies need to support liability awards (liability insurance is either severely limited or unattainable.) One result is that American consumers have to pay about $12 dollars for each cycle of pills. The price could be less than $1 dollar per cycle. Oral contraceptives bought in bulk by the U.S. Agency for International Development (AID) only cost 18 cents per cycle.

It is ironic that the American consumer is denied the IUD, which costs less and is generally safer than the pill, principally because IUD sales in the U.S. have totaled only about $12 million annually whereas the pill generates about $600 million.

In addition to driving existing methods off the market, the liability crisis is stymieing development of new methods. The National Institutes of Health's Center for Population Research has four contraceptive products stalled in research labs because the liability insurance needed to start human testing is unobtainable.

Anti-abortion and Anti-family Planning Activties: Key members of the anti-abortion movement are adding an attack on contraceptives to their battle against abortion. One source of this new thrust is the odd notion that the "contraceptive mentality" leads to the "abortion mentality". Another source is religious fundamentalism, which considers most methods of birth control either highly suspect or patently immoral because sex should be reserved for procreation.

The clout of anti-abortion activists with the Reagan Administration has shut down AID-supported contraceptive development research on certain new birth control methods e.g. a once-a-month pill. More recently these activists have brought pressure on the National Institutes of Health to stop all research on the new French contraceptive drug, RU486, because this product could also be used as a menstrual inducer. Another target is a boycott of Upjohn products because of their work with prostaglandins.

Drug Regulation and the Consumer Movement: The discovery that contraceptive methods such as the pill and the IUD occasionally had serious and sometimes life-threatening side effects heightened the suspicion of some radical feminists and consumer activists that physicians and the pharmaceutical industry were knowingly promoting unsafe contraceptive methods. Unfortunately, the use of any medical drug or device entails risk as well as benefit, but the risk of not using a contraceptive must be weighed against the risk inherent in its use. Risks of contraceptive use are comparatively small. Even in the

West, the health risks associated with contraception (except for pill users over the age of 35 who smoke) are lower than the health risks of pregnancy and childbirth. In Third World countries benefits dramatically oughtweigh potential risks. The complications of pregnancy, childbirth and illegal abortion constitute a leading cause of death among women of reproductive age in developing countries and the risk of death in childbirth is commonly 10 to 100 times greater in these countries than in the West.

Additional research effort is needed to minimize the risks of contraception, but too often the perfect has become the enemy of the good. The U.S. Food and Drug Administration, to some extent, reflects the laudable but unrealistic U.S. penchant for perfection. Because contraceptives are often used for long periods by healthy people, the FDA demands higher standards for safety than for other drugs and devices. The FDA clearly understands that risks of contraceptives must be weighed against benefits. However, there is little penalty for bureaucratic caution and delay, whereas there would be substantial criticism if an "unsafe" drug were approved.

Furthermore, the FDA, at times, responds to political pressure in decision making. Pressure from U.S. feminist and consumer groups undoubtedly has had a role in the FDA's cautious stance on the injectable contraceptive Depo-Provera. Although the FDA asserts that not enough research has been carried out to prove its safety, this judgement is not shared by the World Health Organization (WHO) or the drug regulatory bodies of a number of European countries including: Sweden, Great Britain and Germany. Depo-Provera has been used uneventfully for years in some 80 countries. Even though the Upjohn Company submitted Depo-Provera to the FDA for approval 17 years ago, it continues to wait.

In a regulatory climate that demands proof of safety beyond that required by WHO and other nations, drug companies will continue to be reluctant to commit resources to contraceptive development research. Last year, frustrated by the Depo-Provera experience and anti-abortion inspired boycotts, Upjohn discontinued all contraceptive development research.

Upjohn's disenchantment with contraceptive development research is not unique. Over the past decade, at least a half dozen major U.S. pharmaceutical firms have scaled back or abandoned their efforts in this field. Only a single U.S. company continues a major broad-based contraceptive development research program.

Because the FDA is usually slow to approve new contraceptives other nations have a number of birth control choices not available in the U.S. Canada has a state of the art IUD, Finland has a 4 year implant, and the United Kingdom has an injectable contraceptive.

The U.S. retreat from contraceptive development not only narrows contraceptive choices in the U.S., there is also fallout in the Third World. Some countries severely limit use, or ban use of methods that do not have U.S. approval. The Agency for International Development has a general policy that they will not provide methods for use overseas which are not approved by the FDA. Therefore, AID does not provide Depo-Provera and AID will not provide the new contraceptive implant NORPLANT^R until it has FDA approval.

Fear that critics will accuse the United States of providing "unsafe" drugs has stopped AID from providing life-saving contraceptives. Some 400,000 women lose their lives every year in childbirth in Third World countries. It can be categorically stated that broader use of effective fertility control methods such as NORPLANT^R and Depo-Provera would save many lives. Yet, because of the largely theoretical concerns about their safety, the United States has not acted to make them available overseas in settings where the risk benefit calculus is dramatically weighted in favor of their use.

In dealing with fertility control technology, it is tempting to set aside abortion because it is so controversial. Abortion is undesirable, but availability of safe, legal abortion also reduces infant mortality rates and maternal deaths in all countries because most abortions interrupt high risk pregnancies and eliminate risky illegal procedures.

The demographic consequences of abortion in developing countries are important. Elimination of abortion would increase population growth from 75 to about 100 million each year and boost growth rates by one third from about 2% a year to about 2.7% a year, thereby shortening projected doubling time (at current rates) from 34 years to 26 years.

More research on abortion technology, safety and epidemiology is needed. Furthermore, the best way to cut down on the incidence of abortion is to develop improved contraceptive techniques which are easier to provide and more acceptable to potential users.

What Should Be Done?

Conditions must be made more attractive for private industry to once again vigorously undertake contraceptive research. A step in the right direction was taken last year when patent protection for new drugs was extended up to five years in recognition of lengthy testing periods. The product liability crisis, must be resolved. We must evolve a system which recognizes and expedites valid claims, but also recognizes that decisions made after full and informed consent do entail some degree of risk, whether the product is an automobile, aspirin or birth control.

Drug regulatory requirements need to be reviewed and streamlined. Some experts believe current U.S. drug regulatory procedures overemphasize premarketing testing and do not give enough attention to post-marketing safety surveillance, which would provide accurate and early information about safety and side effects of contraceptives under use conditions. Export of contraceptive drugs and devices which are not approved for U.S. use should be allowed when the risk-benefit ratio overseas is favorable and AID should be allowed to provide such drugs and devices.

Both the U.S. public and the research community have often underestimated the time and cost of contraceptive development. Development of each new method of birth control takes 5 to 15 years and costs between $20 and $70 million.

The worldwide investment in research on reproduction is about $180 million per year, but only $65 to $70 million of this is applied research to develop new contraceptives. Experts estimate that with the current promising leads the field could absorb $500 million per year. In the last decade, the funding trend in constant dollars has been downward. U.S. government outlays for contraceptive development are about $20 million annually, mainly through the National Institutes of Health and the Agency for International Development.

More money to existing government programs would help. NIH and AID together should get at least $50 million more each year for applied contraceptive development research.

But new institutional arrangements are also needed. Vertically integrated contraceptive development programs, similar to those of drug companies, are needed to develop low cost methods that drug firms will never find profitable, e.g. a once-a-year injectable or a ten year implant. A new "Manhattan Project" for contraceptive development is needed with $100 million of private and public funds available each year to allow rapid exploration of the many promising leads which now exist.

Twenty years experience with family planning has taught us that a wide range of contraceptive choices make couples more willing and able to practice voluntary family planning. It is time to call off the war on contraceptives and to initiate a crash program to develop better ones. Better fertility control technology can help to solve important world problems including -- ill health, poverty, and rapid population growth.

Additional Comments of James L. Deger

In oral testimony presented to the subcommittee on May 6, 1986 by the American Life League, it was stated that we would submit to the committee additional comments pertaining to the Title X Federal Birth Control Program.

1. Abortion Performance and Promotion: The present Title X authorization prohibits the use of funds in programs in which abortion is a method of birth control. However, according to a 1983 General Accounting Office (GAO) report and the birth controllers' own admission in hearings conducted by the House Labor, Health and Human Services Appropriations Subcommittee on March 14, 1986, Title X funds are going for programs which promote abortion as a method of birth control/family planning. Further the GAO report showed that some Title X recipients perform abortions, yet are able to continue receiving program funds through various accounting and technical methods which provide abortion services, counsel for abortion services, or refer for abortion services from receiving Title X funding.

It was admitted by Planned Parenthood in the public debate on the amendment and in the hearings cited above, that this wording would effectively prevent the present abuse of the Congressional intent of Title X. Further, in examining the legislative history of Section 1008, we find that Planned Parenthood chairman, Dr. Alan Sweezy, stated before a Senate subcommittee in 1975 that Section 1008 should be modified not only to allow for abortion services, but also for counseling for services. In response to the claim in 1985 that such an amendment would destroy the ability of groups such as Planned Parenthood to provide birth control services, the question was never raised why, if there is a difference between birth control and abortion, Planned Parenthood must be able to promote/provide abortion in order to promote/provide birth control. Clearly, the difference between Planned Parenthood's statements in 1975 and 1985 and their claimed inability to provide birth control without providing abortion should raise clear doubts as to the reliability of their statements.

2. Parental Choice: Under the present conduct of the Title X Birth Control Program, parents are not allowed to exercise their legitimate choices as to their children's sexual actions and use or non-use of birth control. Hence the only adult sanctioned by Congress to advise and provide birth control for minors is the birth control center employee, not the parent. Hence, Congress may want to consider whether parental choice in these matters should be restored. A parental choice policy would also provide for protection of minor children from the immediate and long-range health hazards connected with the use of oral contraceptives and intra-uterine devices (IUD's) which include both venereal diseases and permanent involuntary sterility. Under current HHS guidelines, patients cannot consent to permanent sterilization unless they are 21 years of age or older. With the high incidence of sterility connected with these chemicals and devices, either directly or through contraction of pelvic inflammatory disease, parental consent would increase

the possibility of long-term health concerns being expressed along with the supposed short-term gains from the use of these powerful chemicals and devices. Further, the FDA-mandated physician package insert for oral contraceptives requires that a complete medical history, including family disposition to cancer, be taken before prescribing the birth control pill. What child is fully aware of her own medical history, much less aware of her family's medical history? The answer is obvious--with parental choice restored to Title X, the likelihood of long-lasting health dangers to children would be significantly reduced.

Finally, it is argued by Planned Parenthood and their allies that restoration of parental choice would lead to an increase in pregnancies and abortions among minors. The evidence indicates otherwise. In the state of Utah, for several years, parental choice was required and there was no increase in teen pregnancies, rather there was a marked decrease. Hence the Planned Parenthood claim of increased pregnancy is misleading.

3. School Based Birth Control Outlets: Presently, school based birth control centers are receiving Title X funds. No adequate independent studies have shown that these centers actually assist in reducing the incidence of pregnancy among school children. It has been documented that increased birth control availability increases sexual activity. This being the case, it needs to be asked if this is the proper activity

to be promoted through the nation's school system. The school is not only a place where the three R's are expected to be taught, but also positive and constructive values taught at home are to be reinforced. By facilitating non-marital sexual indulgence, these clinics undermine parental authority and reduce the practice of the most effective method of pregnancy prevention--abstinence.

Proponents of School Birth Control claim parental consent is sought as is the case of DeSable High School in Chicago. However, it should be noted that the consent obtained by parents is not specified consent for birth control services, but blanket consent for all services. In order for a parent to get his/her child other legitimate services provided by some of these outlets, he or she must also consent to birth control availability for their children.

4. Health Protection: At present, Title X grantees are not required to screen for gonorrhea, chlamydia, and other sexually transmitted diseases including Acquired Immune Deficiency Syndrome. It has been clearly shown that there is an increase in the number of sexual partners and sexual intercourse frequency among birth control users and there is an increased incidence in sexually transmitted diseases among birth control users. Wouldn't it be advisable to require regular testing for these diseases in order to improve public health? Twenty years ago, chlamydia was just a textbook oddity. Today, the Center for Disease Control estimates that three million persons a year are

infected by chlamydia. Wouldn't it be wise to mandate screening of high-risk groups such as sexually active single women? And set aside a specific amount of Title X money to accomplish the goal of preserving the reproductive health of American women?

In closing, we thank the Committee for the opportunity to submit additional material at this time.

SUBCOMMITTEE RECESS

Senator INOUYE. The subcommittee will stand in recess until 9:30 a.m. Thursday, May 8, when we will meet again in Senate Dirksen 116 to continue our public witness hearings.

[Whereupon, at 12:30 p.m., Tuesday, May 6, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, May 8.]

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